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ABSTRACT

This publication contains the testimony from a hearing on growth and tobacco use. Statements include: (1) Opening Statement of Senator Bill Frist; (2) Statements of a panel of teens, Brandi Battle, Washington, DC; Kellie Jolly, Tennessee; Nickita Bradley, Maryland; and Josh, Virginia; followed by discussion; (3) Discussion and prepared statements of Scott J. Leischow, Ph.D., Director, Nicotine Dependence Program, Arizona Prevention Center, University of Arizona, Tucson, Arizona; Richard D. Hurt, M.D., Director, Nicotine Dependence Center, Mayo Clinic, Rochester, Minnesota; Michael C. Fiore, M.D., M.P.H., Panel Chair Smoking Prevention and Cessation, Agency for Health Care Policy and Research, and Director and Associate Professor, center for Tobacco Research and Intervention, University of Wisconsin Medical School, Madison, Wisconsin; and Tim McAfee, M.D., M.P.H., Director, Center for Health Promotion, Group Health Cooperative of Puget Sound-Kaiser, Seattle, Washington; (4) Prepared Statement of Senator Mike Enzi; (5) Discussion and prepared statements of Paul Schwab, Deputy Administrator, Substance Abuse and Mental Health Services Administration, Rockville, Maryland; and Joseph R. DiFranza, M.D., University of Massachusetts Medical Center, Boston, Massachusetts. (EMK)

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PUBLIC FORUM ON YOUTH AND TOBACCO: BREAKING THE CYCLE

HEARING

BEFORE THE

SUBCOMMITTEE ON PUBLIC HEALTH AND SAFETY

OF THE

COMMITTEE ON
LABOR AND HUMAN RESOURCES
UNITED STATES SENATE

ONE HUNDRED FIFTH CONGRESS

FIRST SESSION

ON

EXAMINING PROPOSALS TO DETER YOUTH FROM USING TOBACCO
PRODUCTS

OCTOBER 27, 1997

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PUBLIC FORUM ON YOUTH AND TOBACCO: BREAKING THE CYCLE

MONDAY, OCTOBER 27, 1997

**U.S. SENATE,
SUBCOMMITTEE ON PUBLIC HEALTH AND SAFETY, OF THE
COMMITTEE ON LABOR AND HUMAN RESOURCES,
Washington, DC.**

The subcommittee met, pursuant to notice, at 2:03 p.m., in room SD-430, Dirksen Senate Office Building, Senator Bill Frist (chairman of the subcommittee) presiding.

Present: Senators Frist, DeWine, Collins, and Bingaman.

OPENING STATEMENT OF SENATOR FRIST

Senator FRIST. This hearing of the Senator Labor and Human Resources Committee, Subcommittee on Public Health and Safety will come to order.

I am very pleased that we have the opportunity to step back for a moment from the general political morass surrounding the global tobacco settlement because today we are going to focus on those fundamental strategies to reduce teen smoking that will undoubtedly be incorporated into any youth tobacco policy, with or without a settlement.

In addition, we want to receive the benefit of the very best science, the very best scientific research on the physiology of nicotine addiction and determine what we know and what we do not yet know about nicotine's effects on the body, and particularly on the body of a young person.

The full committee, through the outstanding work of our chairman, Chairman Jeffords, has done a commendable job on focusing attention on youth smoking. In a coordinated effort, we at the subcommittee level, as the Subcommittee on Public Health and Safety, will attempt to determine how best to use the resources of the public health agencies that come under this subcommittee's jurisdiction in the war on youth smoking.

In recent days, many have remarked that it would take the wisdom of Solomon to navigate the complexities of this issue, yet our task is still to move with all deliberate speed. As Solomon wrote in Proverbs, it is not good to have zeal without knowledge, nor to be hasty and miss the way.

But before we wrestle with the research issues and the science and how best to interpret that science, we are honored to have with us today four young people on our first panel who have agreed to testify about their personal experiences with smoking. Their stories

(1)

are compelling. The lessons they will teach us will be invaluable for us as policy makers, and I want to thank each of them for taking time to come forward and participate in this process of democracy.

We expect to learn a great deal from them about the importance of community-based initiatives. Experience has taught us to temper our expectations of what government by itself can achieve. We must look to our social institutions, our civic institutions, and partner with families and schools and churches and neighborhoods to stop teen tobacco use.

It is clear to all people concerned that we are not doing enough now. Each year, an additional one million young people become regular smokers. As we hear from the scientific experts on the physiological implications of smoking, our goal will be to direct taxpayer dollars toward scientific strategies rather than bureaucratic nonsolutions. Any campaign must be grounded in a thoughtful review of existing science and a clear-headed respect for the difficulty of affecting teenage behavior, behaviors of all types.

Research shows that three out of four adolescent smokers have made at least one serious attempt to stop smoking, yet have failed. In addition, at least 50 percent of young people report that they made their first attempt to stop smoking within 2 years of their first cigarette. What role do cessation programs have in targeted efforts toward the adolescent population, and what about compliance checks? Do they work? Have we perfected the science of sting operations?

These are some of the questions we will explore today. We have already learned that there are no easy answers, so we must now renew our commitment to tackle this issue with integrity and with creativity. Once we find the best answers, we must implement them with a minimum of partisan wrangling.

As a heart surgeon, as a lung surgeon, as a father to three boys, I am very concerned about the issue. I tell every one of my patients not to smoke, and if they have already started smoking, to stop smoking. There is a clear link between smoking and cancer and heart disease and other diseases.

Yet despite the great public outcry in this country against smoking, particularly against teen smoking, we have not even begun to apply all at our public health and private resources, especially at the community level. I am grateful for the attention this issue is receiving and look forward to the interaction that we will have today.

To allow maximum time for our witnesses, we will follow the committee policy with regard to opening statements, which will be made at the time of questioning. In addition, I ask members to keep their remarks to approximately five minutes per panel. I urge our witnesses today to make brief statements of no more than five minutes' duration.

The hearing record will remain open for individual submissions of written testimony relating to the subject of this hearing. Testimony should be no more than ten pages in length. The hearing record will remain open until November 3, at which time it will be closed.

At this juncture, I would like to ask our first panel to come forward, and you have name tags there. The first panel consists of

four young people who will present their unique perspectives on smoking.

I have just been notified from the floor that the Democrats have objected to all meetings of all committees in the U.S. Senate, effective right now. Therefore, I ask unanimous consent to insert the materials from—we will continue in an informal meeting, but I will insert all of the testimony today into our records, and at this point, I would ask unanimous consent to do that. Without objection, we will be inserting materials in the record and we will proceed informally, understanding the objection to all committee meetings.

With that, let me turn to the first panel. Brandi is a 14-year-old from Washington, DC, who will be sharing with us how her church youth group, the Youth for Christ from the Anacostia Gospel Church, has influenced her decision about whether to smoke. This church's outstanding work in the DC. inner city has been prominently featured in the media.

Kellie from Sparta, TN, is a 20-year-old member of the national champion women's basketball team at the University of Tennessee. She will be talking to us about how participation in athletics steers teens away from smoking.

Nickita is an 18-year-old from Maryland who began smoking at age 14 but stopped 2 years later. She will be relating how her experience with pregnancy and motherhood affected her decision to quit.

Finally, we will hear from Josh, who is 16 years old. Josh is a current smoker whose story will help us better understand the factors behind youth smoking.

With that, I will turn to Brandi and we will move straight down the line. Brandi, welcome, and thank you for being with us today.

STATEMENTS OF BRANDI BATTLE, WASHINGTON, DC; KELLIE JOLLY, TENNESSEE; NICKITA BRADLEY, MARYLAND; AND JOSH, VIRGINIA

Ms. BATTLE. Good afternoon. My name is Brandi Battle. I am 14 years old and I am in the ninth grade at Patricia Roberts Harris Educational Center in Southeast Washington, DC. I am speaking to you today on behalf of myself and the youth at Anacostia Gospel Chapel.

As you know, smoking is very hazardous to your health. Smoking can make you very sick. It can cause cancer. I once saw a picture in science class of two lungs, one of a smoker and one of a non-smoker. The visual comparison was astonishing. One lung of the smoker was as black as tar. One of the nonsmoker was pink and perfectly normal. This shows how harmful smoking is and how it can shorten your life.

Some people start smoking because they are looking for acceptance from their peers. Other kids smoke because they watch their parents smoke, so they follow their parents' examples. My mother smoked and her father smoked, too. Many of my relatives smoke on both sides of the family. It seems natural that I would start smoking, also.

However, I have made a commitment not to smoke for many reasons. As the daughter of a smoker, I know that smoking affects not only the smokers but also those who live with them. The smell of

smoke gets in everything, the air, clothing, and hair. Victims of fire often die from smoke inhalation, but I live with it every day. As an athlete, I need to keep a strong and healthy body. Smoking will prevent me from doing my very best. I have never personally seen anyone die from smoking, but each day, I watch my mother smoke herself into an early grave.

As an educated black woman, I do not wish to begin an expensive, addictive habit that will give me bad breath, stained teeth, irritated eyes, headaches, and shortness of breath. As a young woman of faith, I will not start smoking because I want to obey God's word. I do not wish to defile his temple, which is my body. I am too smart to begin a lifestyle that is self-destructive. Some people may get pleasure and satisfaction from smoking. My satisfaction comes not from smoking but from the personal relationship with Jesus Christ.

Senator FRIST. Brandi, thank you.
Kellie.

STATEMENT OF KELLIE JOLLY

Ms. JOLLY. Thank you, Senator. I personally have grown up in a nonsmoking home and, therefore, I have not been subject to smokers, but I have never considered smoking. I have more of a reason not to smoke because I am an athlete. I have to take precautions to keep myself healthy so that I can reach my peak performance. Basketball has provided me with many opportunities, and I must stay healthy to reach my goals.

I know that even a light smoker can feel respiratory strain and a reduction in performance. As my trainer has passed along to me, I know that carbon monoxide, which is a component in smoke, limits the oxygen carried into the blood stream. Therefore, maximum exercise capacity is lowered.

Nicotine increases the resistance of air flow in and out of the lungs by constricting the airways. Smoking also paralyzes the cilia in the lungs, and the cilia is responsible for clearing and removing debris in from the lungs. Therefore, the debris is accumulated when the cilia is not functioning.

By playing sports, I think athletes are more likely to refrain from smoking and I think that athletes are going to do what is best for their bodies and I do not think it should be any different from anyone else.

Senator FRIST. Thank you, Kellie.
Nickita.

STATEMENT OF NICKITA BRADLEY

Ms. BRADLEY. Good afternoon, Mr. Chairman. My name is Nickita Bradley and with me is my son, Patrick. I am 18 years old and live in Baltimore City.

Like so many other teens in my community, I began smoking when I was 14 years old. At that time, because of pressure from my friends and family and other things happening in my life, smoking seemed to be the thing to do. Two years later, I was still smoking and found out that I was pregnant. I continued to smoke during the first 2 months of my pregnancy and then I quit. It was

very hard to stop smoking. I tried the patch and the gum, but none seemed to work, but then I just quit "cold turkey".

Let me tell you why I quit. My mother has been a smoker most of her life, and although I feel healthy, I do have asthma. It is not clear to me whether my mother's smoking contributed to this or not, but enough. I have an older brother named Marquis who was a premature, low birth weight baby. Today, he still has certain disabilities in his life. We will never know what effects my mother's smoking had on his health problems.

Based on this experience, I was determined to do everything I could to give birth to a healthy baby. I owed it to my baby to stop smoking, and I am proud to say that Patrick weighed eight pounds, nine ounces at birth and is still healthy.

Smoking is a terrible habit. It messes with your health, but there is a lot of pressure put on teens from their friends to join the crowd and become a smoker.

Let me finish by telling you what the Baltimore City Healthy Start Program means to me. It is a great program that helps build character. It shows women and teens how to be a caring mother. Healthy Start helped me with setting goals for my future. I just finished my GED classes at Healthy Start Center. Also, I am looking forward to going to school to be a culinary artist in the near future.

As a nonsmoker and a current mother, my life is on the right track. Thank you so much.

Senator FRIST. Thank you, Nickita.

Josh, welcome.

STATEMENT OF JOSH

JOSH. Good afternoon. My name is Josh and I live in Virginia. I am 16 years old and I am in the 11th grade.

My first experience with smoking was when I was about 9 years old. My little brother and I were wondering what it was like to smoke, so we got one of my dad's packs of cigarettes and brought it in the back yard and tried to smoke. We did not know how, so we could not get it lit. We were trying to blow out instead of drawing in. My dad found out and he made me sit inside and smoke several cigarettes in thinking this would prevent me from wanting to smoke anymore. I felt really sick that night, and so for a long time, I did not even go near cigarettes.

The next experience I had was when I was with one of my friends. He had gotten a pack of cigarettes, and so we went into his backyard and smoked a few. It was not really fun or anything. I was just smoking because of the whole peer pressure thing. But every once in a while when we got together, we had one. We would go around the corner or whatever and smoke a cigarette. I stopped when I stopped hanging out with him about four or 5 months later.

After that, I did not really smoke for about a year, until I was about 12. How I got started was 1 day when I was outside, I found one of my dad's cigarette butts that had not had much smoked off of it. I was interested in trying it out again, so I brought it into the backyard and smoked it. I got a buzz and thought it was cool, so from then on, I would look for half-smoked cigarettes to smoke. I did not know why. They taste pretty bad.

But then I started sneaking packs from my dad. Sometimes he would notice and ask me and my brother about it. I would deny anything about it and he would believe me. I got to where I was smoking pretty regularly. Sometimes my parents would pick up on it, smelling it on me. I got in trouble when they smelled it on me, so I had to be pretty careful about it.

Then I started meeting people and found out how to get cigarettes, and from then on, I smoked Camels. I was smoking about half a pack a day and I was always in trouble with my parents about it and getting grounded for it. This went on for a long time. Finally, they pretty much got tired of the constant conflict and just let me smoke. They figured I was just going to do it anyway and I had not listened to them over the past year. So I continued to smoke and just did not let them see me smoking and it was just left at that. My parents were worried about me asking strangers to buy me cigarettes, so they started buying them for me with my money.

Right now, I smoke from a half a pack a day to one pack. I have tried to quit a couple of times using the patch and nicotine gum because my parents were really getting on me about trying to quit. So I gave it a try, but it did not work. I guess I did not really want to quit. It is more of a mental thing than a physical thing. I crave the actual physical part of smoking, inhaling it and having it in my hand, plus a lot of my friends smoke. I am sure I will want to quit sometime, I am just not sure when.

Senator FRIST. Josh, thank you very much.

I thank all of you for your comments, and what I would like to do is spend a few minutes among all of us and just have a discussion and bring out some of the points that many of you have mentioned, and the range is really wonderful. This is the most important panel today. If we do our job as policy makers, our job is to reduce and ultimately eliminate teen smoking, so I want to thank all of you for taking time to come and share your thoughts and your feelings and attitudes with us.

Brandi, I want to begin by saying what a great example you are for people all across America. Your family and your friends must be very proud of you. I do want to ask you a little bit about the pressures that you must resist day in, day out, not to smoke, against smoking. Do many of your friends smoke right now?

Ms. BATTLE. No.

Senator FRIST. So one out of ten, or one out of five, or—

Ms. BATTLE. Out of five.

Senator FRIST. One out of five. Why do you think more of them do not smoke?

Ms. BATTLE. They are not around people who smoke all the time. They are just their own person.

Senator FRIST. And then right now, are you ever pressured day in, day out, to smoke? Do people come up and say, "Brandi, why are you not smoking? We are out smoking." Do you feel that pressure at all?

Ms. BATTLE. No.

Senator FRIST. Let me ask you, Brandi, and then, Josh, maybe you, as well, about advertising. It is something that we talk about in these rooms day in, day out, the importance of advertising, the

importance of Joe Camel, the importance of billboards. Josh, let me ask you, do you feel any pressures to smoke or not to smoke, and also I am thinking of your friends, as well. You said that you have tried to stop smoking, that you do smoke, and will try to stop again in the future probably at some point. What is the role of advertising, the billboards, and what do your friends say about it?

JOSH. Most of the advertising that I have gotten is from, like, looking at magazines and stuff, but I do not really talk much about my friends, why they—what brand they picked and stuff. Right now, I am smoking Newports just because all my friends do smoke Newports. I do not know. The reason why I picked Camels was it appealed to me at the time and it had the “Camel cash” on the back and I thought that was cool, but—

Senator FRIST. And Brandi, what about you? When you see those billboards and the magazines and the advertising, again, answer for yourself but also your friends, what is your impression in terms of the importance of that advertising?

Ms. BATTLE. I do not feel any pressure because I just see what it does to other people and my mother, and my friends are basically my age, so they do not really think about smoking. They just thinking about what they can wear to school and mostly just doing their work, I guess.

Senator FRIST. Nickita, how would you answer that in terms of the advertising and billboards and magazines? Do you think that influences people your age to start smoking?

Ms. BRADLEY. I feel as though it does very much that. As for myself, I do not take notice to the billboards. I feel as though it is just another opportunity to get people to smoke, but I feel also that I never paid any notice to it.

Senator FRIST. Kellie, clearly, being in athletics, you found it to be an environment in which smoking is not encouraged and where there is clearly a detrimental effect to your performance if you did smoke. Do you have many friends who smoke? Obviously, you spend a lot of time with basketball, but outside of that?

Ms. JOLLY. No. I do not have any close friends that smoke.

Senator FRIST. Have you ever smoked?

Ms. JOLLY. I have never smoked in my life.

Senator FRIST. Are there community efforts? I think it is unusual. Again, sports puts you in that sort of environment. Is there anything going on in your community that would either encourage or discourage people from smoking, or is it predominately athletics?

Ms. JOLLY. I think that community, involving youths, I think where I am from, athletics is a big part of what youths do and, therefore, it keeps them busy with something else and they are not getting pressured from friends to smoke. I know that when I was in high school, the people that did smoke were the people that had nothing to do after school, that were not involved with extra-curricular activities, and whose family background were smokers.

Senator FRIST. Thank you.

Senator DeWine.

Senator DEWINE. Mr. Chairman, thank you very much. Let me congratulate you for putting this hearing together. I think it gets right to the questions that we really need to ask, and that is, as we look at this proposed tobacco settlement and as Congress looks

at this, to me, the most important question is the question that we are raising today, and that is, what can we do to slow down the growth in teenage smoking and to get young people to stop smoking, and more importantly, to see that they do not begin to smoke at all. So I think the hearing is an excellent hearing. I think this panel has been a very excellent panel. I just have several questions.

Josh, you indicated that, I think I heard you say your parents now get your cigarettes for you. Where did you get them before, though, when you first started regularly smoking?

JOSH. Actually, I had a friend who had a fake I.D. and he used to buy cigarettes for some of my friends and people.

Senator DEWINE. How old was he at the time?

JOSH. Sixteen.

Senator DEWINE. He was 16 and he had a fake I.D., so he would buy them for you and for his other friends, then?

JOSH. Yes, sir.

Senator DEWINE. How about vending machines? Did you use vending machines?

JOSH. A few times. Nobody really watched those too closely, so—

Senator DEWINE. I am sorry. I did not hear you.

JOSH. Nobody really watches those too closely, so when nobody was around and I did not have any, I would just go to a vending machine, yes.

Senator DEWINE. Nickita, when you were smoking, where did you get your cigarettes?

Ms. BRADLEY. I would normally get my cigarettes from the store because I had never had no problem with age, because people in my community as young as 9 years old go to the store and get cigarettes. There is no—they do not ask for I.D.s. They do not ask for anything. It is a shame, because they will have the paper on the store wall that said, you must be this old to get them, but the customers and the people who work there do not pay that any attention.

Senator DEWINE. So you just walk into the store and just make the purchase?

Ms. BRADLEY. Yes.

Senator DEWINE. And this would be people even, you said, younger than you, is that right?

Ms. BRADLEY. Yes.

Senator DEWINE. Or younger than you were at that time?

Ms. BRADLEY. Yes.

Senator DEWINE. What cigarettes did you smoke when you smoked?

Ms. BRADLEY. I smoked Kools and Newports.

Senator DEWINE. Why did you choose those?

Ms. BRADLEY. Because I got hooked on Kools, but I heard of the fiberglass that they had in it, and it is like it would mess up your lungs badder than Newports, I mean, badder than anything else, so I switched to Newports.

Senator DEWINE. And Josh, you said that you started with Camel?

JOSH. Yes.

Senator DEWINE. Why did you tell us you started with Camel?

JOSH. I do not know. It was most of my friends who did smoke smoked either Marlboro reds or Camels and I did not really like the taste of reds, so I just smoked Camels.

Senator DEWINE. We have heard a lot of talk about Joe Camel and the advertising. Can you tell us whether that had any effect on you, or do you know whether it did or not?

JOSH. Maybe just because I was exposed to it a lot, possibly, but I did not really look at the ads and say, whoa, Joe Camel is cool, but it might have had an influence, just because I read Hot Rod magazine a lot and there are a lot of Camel ads in those, more than other cigarettes.

Senator DEWINE. Thank you very much. Thank you, Mr. Chairman.

Senator FRIST. Senator Collins.

Senator COLLINS. Thank you very much, Mr. Chairman. I want to thank you for calling this hearing today to discuss youth anti-smoking initiatives, and I certainly agree with your comment that we are hearing from experts in this panel.

While adult smoking has declined in recent years, teenage smoking has risen sharply. Tobacco addiction is increasingly a teen-onset disease. Indeed, 90 percent of all smokers start before they are 21. If we are going to put an end to the tragic and yet preventable epidemic, I think we need to accelerate our efforts not only to help more smokers like Josh to quit, but also to discourage young people like Brandi from lighting up in the first place.

Unfortunately, Mr. Chairman, Maine has the dubious distinction of having the highest smoking rate among 18- to 34-year-olds in the Nation. I think most people would sort of intuitively think it would be Mississippi or Kentucky or some State that grows tobacco, but unfortunately, it is my own State of Maine. So this is an issue that I am particularly committed to exploring.

We have a situation in Maine where more than 31,000 of Maine's young people currently under the age of 18 will die prematurely from tobacco-related disease. So I am very pleased to have the opportunity to ask our experts a few questions this afternoon, and I agree with the Senator from Ohio that my number one concern in looking at the proposed tobacco settlement is assessing what the impact will be on our terribly high rate of teen smoking.

I would like to start with Josh, since you are the current smoker on the panel. When you were younger, did your school have a DARE program or some sort of anti-smoking education program?

JOSH. Well, actually, I was home schooled until I was in the 10th grade.

Senator COLLINS. What about you, Nickita, since you used to smoke? Did your school have any sort of program? There is a program called the DARE program and there are other anti-smoking programs, that taught you that smoking was bad when you were very young?

Ms. BRADLEY. None whatsoever.

Senator COLLINS. None whatsoever. Kellie, how about you?

Ms. JOLLY. We had the DARE program, and I know that the DARE program is still going on in my county today.

Senator COLLINS. Brandi, was there any sort of DARE program in your school—you are not high school, I know, yet—in your elementary schools or middle schools?

Ms. BATTLE. No.

Senator COLLINS. What I am trying to get at is in Maine, the DARE program is very active and it seems to work very well when the children are very young, and then something seems to happen as you all get older and all of a sudden, children who are very anti-smoking become very interested in smoking. I would like to figure out what happens, because if we do not figure out what happens in those middle school years, we are not going to be able to target our response effectively.

So I would appreciate it if you could try to tell me what happens. Is it peer pressure? Is it seeing Brad Pitt and Julia Roberts light up on the movies or in magazines? What happens to change the attitudes of students from being very anti-smoking when they are under age 10, say, to thinking that smoking is cool when they get in their teen years? I am going to start with you, Josh, and then go down the panel.

JOSH. I think that is true, because when I was, like, about grade school level, both of my parents smoked, but I was really against it and I asked my dad why he smoked and asked him if he would quit and stuff like that and they were very against, like, they would talk to me about not smoking and how bad it was. When I hit about, I guess, 11, I mean, part of the movie actor start of stuff, that does, I think, play a role in starting to smoke, because it does look kind of cool when people, like, you look up to, like you want to be like when you grow up, do light up on screen, and it just appealed to me, and partly from peer pressure. And I think teenagers, or when you are reaching that age, just, I mean, you get interested and you try new stuff out.

Senator COLLINS. Nickita.

Ms. BRADLEY. Also, my parents had smoked and I would encourage them not to smoke. I would tell them what smoking has done or do to them. For a while, I was anti-smoking, but my best friend and all the friends around me were smoking and I felt left out, so that is the pretty reason why I started, and they started smoking because they thought it was the grown-up thing to do. It would be cool. They would be popular. I just wanted to be along with the crowd.

Senator COLLINS. Kellie.

Ms. JOLLY. I believe that kids during this age are trying to become older quicker than they actually are. They are looking for ways to grow up. It is a hard time, I think. It is a transitional period. They see adults smoking and they think it is cool. I think that when one person starts, that is when the peer pressure begins and it has a snowball effect.

Senator COLLINS. Brandi.

Ms. BATTLE. I think television has a lot to do with it, because when you watch TV and you watch certain shows and cartoons, the cartoon characters are smoking and laughing about it and your parents talk and laugh about it and they think that they can talk to their friends and laugh about it and it is just going to be funny.

Senator COLLINS. Hearing what you are saying, I think we need a counter-advertising campaign, and I am wondering if we are pitching it the wrong way when we tell people, well, you could die from cancer or you could get some horrible disease when you are older, because older is a long ways away for all of you. Telling you that you might die early years from now does not have a lot of meaning. I am wondering, and one of you said it, that you did not want to have your breath stink or get your teeth stained or turn yellow, I wonder if our emphasis should be more that way.

What message could we have sent you, Josh, that would have helped to counter the fact that—to help you resist the allure of smoking when your friends were smoking and you were seeing your parents smoke, too?

JOSH. Probably more the immediate effects, like short-term, instead of you are going to get lung cancer when you are an adult, like you are not going to be able to run, play games, do sports, whatever, stuff like that. I think that would work better than saying something like, you are not going to live as long.

Senator COLLINS. Kellie, do you agree with that, because it sounds like you got a strong anti-smoking message through your involvement in sports, that you were not going to be as good an athlete?

Ms. JOLLY. Yes, I do. I think that the immediate effects of smoking would have more of an impact on young kids than the long-term effects, because at that age, we feel invulnerable.

Senator COLLINS. I remember being that way. Brandi, it sounds like your religion has helped you be strong and resist that peer pressure, is that right?

Ms. BATTLE. Yes.

Senator COLLINS. Any other advice to us on how we could help the youth of America say no?

Ms. BATTLE. I guess what other people can do is take them through like a hospital and show them what people are dying from, just to see them with the person that smokes all the time and every day of their life and now they are in the hospital dying from lung cancer, just to take them and show them what can happen to them if they keep going what they are doing. I think that will change their minds just a little.

Senator COLLINS. Thank you.

Nickita, do you have anything to add? How could we have reached you when you were at that vulnerable age and deciding to smoke because your friends did and you did not want to feel left out, as you put it?

Ms. BRADLEY. Well, basically, there was really nothing that anybody could do because I felt as though you were going to die from something anyway. Basically, I did not know what to do. The only thing that helped me was my mother, when she told me how she was smoking and how my brother turned out. He was very premature and he is like, slow, now. He is 21. He has the mind of a 10-year-old. I did not want my child to, like, come out so severe and so distraught and hurt, so I had to stop smoking because of that.

Healthy Start really helped me stop smoking. They gave me pamphlets. They actually sat down and talked to me about smoking and what it could do to your child, because they did not want

nothing happening to my child whatsoever. So that is basically why I stopped and that is the only thing that did help me stop.

Senator COLLINS. Thank you very much, Mr. Chairman, and thank you for sharing your experiences with us.

Senator FRIST. Thank you. Senator Bingaman?

Senator BINGAMAN. Thank you, Mr. Chairman. I did not have questions of this panel. I appreciate them being here and look forward to hearing the rest of the testimony today, as well. Thank you.

Senator FRIST. Let me just close the panel with two other questions. Josh, we are going to have a panel right after this on smoking cessation, and again, this is sort of a prelude and the heart of what we are going to be talking about in the next two panels. You have mentioned that you had tried to quit, and Nickita, you have been successful in quitting. Josh, tell us a little bit about your attempts to quit smoking and why you think you were unsuccessful in those attempts thus far.

JOSH. Well, the reason why I tried to stop was because I could tell that my mom was just, like, really upset about me smoking and both my parents were the same way. I was, like, well, if they are not going to be so distraught about it, then I might as well try. But it did not work because I do not think I really wanted to quit, like I felt more like, well, for now, all my friends smoke and I do not think that I would be able to quit for long and I just—it did not really work that well.

Senator FRIST. If you were a parent, what would you do if you had a son or a daughter who was smoking? What advice would you give to the many of us who are parents, as well?

JOSH. That is kind of hard. I would try very hard just to keep them away from smoking. I mean, if I had kids, I would probably try a lot harder to quit, just to keep them away from it, just because I know what it does to you. If they were already smoking and they were teenagers, like around 15 or 16, and they still did not quit and it did not look like they were going to, it is their decision, and if they are not going to quit and they are just really going to smoke and they are into it, then I do not think there is any way that you can stop them except to just let them know how much you are hurt by it. That was pretty much the only thing that really got to me, was that it hurt my mom so much, and my dad.

Senator FRIST. One last question, and I would like all of you to take a crack at it. If you were in the place of all of us sitting up here and had a real clear objective, and that is to prevent teen smoking, adolescent smoking, and I guess if smoking, had already begun to stop it, what law would you write that would discourage young people from smoking, from using tobacco? We talked a little bit about advertising. We could talk about vending machines. We could talk about access to the stores, being able to purchase.

There are lots of things we could do, but what advice would you give us? What kind of law could we write, based on your firsthand experience with the age group, that would discourage people from smoking or prevent them from smoking? Let me give anybody the chance to open up, and I want each of you to take a crack at it. Brandi, do you want to begin?

Ms. BATTLE. The vending machines that are in stores, some stores have locks on their cabinet and you cannot get in it unless you go and ask someone, so I think that if more stores had that kind of security about their cigarettes, then I think that young kids would not be able to go into as many stores and get their cigarettes from the stores.

Senator FRIST. Do you mean vending machines themselves, or just stores, accessing the stores generally?

Ms. BATTLE. Generally, the stores.

Senator FRIST. All right. Kellie, what do you think?

Ms. JOLLY. I think trying to strengthen the policies where minors are getting these tobacco products. It really blows my mind that young kids can go in and buy cigarettes and tobacco products.

Senator FRIST. Nickita?

Ms. BRADLEY. I actually feel that of any penalty, that minors should not be able to buy cigarettes under the age of 21, and for any adult who buys cigarettes for the minors, must pay the price of paying a penalty or going to jail. Basically for the vending machines, have the vending machines not on the outside of the store but in the inside. You must ask to buy, and as well for adults who buy for the kids must pay a price.

Senator FRIST. Do you think a penalty such as losing your driver's license is the sort of penalty that would discourage you from smoking or stop smoking?

Ms. BRADLEY. Well, basically, yes and no, because some people do not even have cars. So if people who do have cars, they are shifted away from all the people who do not have cars. They should find some other kind of punishment to give them.

Senator FRIST. Josh.

JOSH. I really think vending machines are pretty pointless. I mean, if you are going to go to a store and go get it from a vending machine, you might as well go to the register and get yourself a pack, except in, like, situations where in the smoking section of a restaurant, where if somebody is out of a pack of cigarettes and they are of age, they could just go to the vending machine and get a pack.

I think penalties like stricter penalties for selling to minors, because, I mean, a lot of people—I do not know why people sell to kids, if they are just—I do not really know their motives or what not, but if the penalties were stricter, I believe they would not sell to minors as much.

Senator FRIST. Can you get cigarettes easily from a store or vending machine? Do you have any problems with access, or your friends?

JOSH. There are particular stores where, like, pretty much everybody who smokes knows where to go to get them, like a couple gas stations or something like that where you can go and people know that they are just not going to card you.

Senator FRIST. So in your neighborhood, there are stores that you know you cannot go and there are stores you know you can go, is that right?

JOSH. Yes.

Senator FRIST. So in terms of getting cigarettes, that is not a problem?

JOSH. Yes, pretty much.

Senator FRIST. Any final questions? If not, thank you all. I have said it, and I will say it one final time. To have you participate in this very direct way helps us tremendously as we tackle these very tough challenges, and I want to thank each of you for taking time to be with us. Thank you very much.

I will ask our second panel to come forward. We will hear from four distinguished scientists who will present a flavor of the current medical approaches toward overcoming nicotine addiction and promoting smoking cessation.

Our first witness is Dr. Scott Leischow. He is currently an Associate Professor at the University of Arizona College of Medicine, where he is Director of the Health Education and Health Promotion Unit, as well as Director of the Arizona Program for Nicotine and Tobacco Research. He has published extensively on the pharmacologic treatment of nicotine addiction.

Our second panelist is Dr. Richard Hurt from the Mayo Clinic. Dr. Hurt is Associate Professor of Internal Medicine at the Mayo Medical School and Director of the Mayo Nicotine Dependence Center. He has published numerous articles on nicotine dependence and treatment, is a fellow of the American College of Physicians, board certified in internal medicine and addiction medicine.

Our third witness, Dr. Michael Fiore, is an Association Professor in the Department of Medicine at the University of Wisconsin Medical School and Director of the Center for Tobacco Research and Intervention. His background includes training not only as a physician but also as an epidemiologist. The focus of his work has been the development of strategies to promote intervention by clinicians and others to assist smokers.

In addition to publishing extensively on tobacco, Dr. Fiore continues to care for patients and his busy schedule has included service as consultant to the National Cancer Institute, Chair of the AHCPR Panel on Clinical Practice Guidelines on Smoking Cessation, and Director of the Robert Wood Johnson Foundation National Program office on addressing tobacco in managed care.

Our fourth panelist is Dr. Tim McAfee, a family practice physician in Group Health Cooperative in Seattle and the Medical Director of Tobacco Prevention Services. Dr. McAfee is a faculty member at the University of Washington, with a background in epidemiology. His focus has been the development of innovative strategies to decrease tobacco use, including financing of smoking cessation, clinic-based and telephone-based interventions, and approaches through the media.

Dr. Leischow?

STATEMENTS OF SCOTT J. LEISCHOW, PH.D., DIRECTOR, NICOTINE DEPENDENCE PROGRAM, ARIZONA PREVENTION CENTER, UNIVERSITY OF ARIZONA, TUCSON, AZ; RICHARD D. HURT, M.D., DIRECTOR, NICOTINE DEPENDENCE CENTER, MAYO CLINIC, ROCHESTER, MN; MICHAEL C. FIORE, M.D., M.P.H., PANEL CHAIR, SMOKING PREVENTION AND CESSATION, AGENCY FOR HEALTH CARE POLICY AND RESEARCH, AND DIRECTOR AND ASSOCIATE PROFESSOR, CENTER FOR TOBACCO RESEARCH AND INTERVENTION, UNIVERSITY OF WISCONSIN MEDICAL SCHOOL, MADISON, WI; AND TIM McAFEE, M.D., M.P.H., DIRECTOR, CENTER FOR HEALTH PROMOTION, GROUP HEALTH COOPERATIVE OF PUGET SOUND-KAISER, SEATTLE, WA

Mr. LEISCHOW. Good afternoon, Mr. Chairman and members of the committee. I am grateful to have the opportunity to participate in this hearing on youth nicotine addiction.

We conduct clinical research to evaluate the safety and efficacy of medications for smoking cessation at the University of Arizona. We have a toll-free telephone-based tobacco counseling service for both youth and adults and we actively use the Internet to communicate and educate about the risks of tobacco use and how to quit tobacco. Our activities in Arizona range from prevention to treatment and involve health care systems, schools, and work sites, so we do pretty comprehensive work there.

As we know, nicotine addiction is a pediatric disease that is both pervasive and profound. While we cannot accurately predict who will use tobacco or become addicted to nicotine, one very interesting pattern has begun to emerge from research.

We know that the average age youth begin using tobacco is about 14, which, of course, is also an important time developmentally, but what we are also finding is that youth who are at greatest risk for developing nicotine addiction are also those who suffer from depression, anxiety, or attention deficit hyperactivity disorder. Some researchers have speculated that youth who move beyond experimental use of tobacco may, in effect, be self-treating their psychological discomfort, since it is known that nicotine use can have a calming effect.

Speculation on the possibility of shared neurophysiologic pathways for depression, anxiety, and ADHD and nicotine addiction is supported in another way, as well. The FDA has recently approved the use of bupropion, a nonnicotine medication that seems to enhance dopamine levels as an effective smoking cessation treatment for adults and it is now on the market. This same medication has been available for several years as an anti-depressant.

In addition, two preliminary studies have found that bupropion also appears to be effective for the treatment of ADHD. The efficacy of this medication for several disorders that have been found to be clustered together with youth tobacco use reinforces the notion that there must be some common pathways. We just do not know for certain what those pathways are yet and only continued research effort can eventually answer that question.

Given this phenomenon, we have speculated at our clinic that use of bupropion may very well be an effective smoking cessation treatment for youth, as well, and through the support of the Na-

tional Cancer Institute, we have just embarked on a study to evaluate the safety and efficacy of bupropion for that purpose.

Several areas of research warrant further exploration, some of which I will touch on and others my colleagues will discuss. Continued exploration of psychiatric co-morbidities, including other forms of substance abuse, are essential in order to ultimately develop a full understanding of the mechanisms that control nicotine addiction, particularly since the vast majority of those who become addicted do so before the age of 18. The exploration of socio-cultural factors that influence initiation and continuation of tobacco use is, likewise, necessary, including the impact of socio-economic status, peer influence, advertising, tobacco costs, and social sanctions.

While we continue to explore factors associated with tobacco initiation and addiction, tobacco use prevention and treatment research must move ahead, since there is no firm consensus from the research community on what works for youth tobacco prevention and cessation. The National Cancer Institute is to be commended for taking a lead on research in this area, since they have recently funded 15 new grants to investigate tobacco use predictors, prevention, and treatment in youth and will fund additional research next year.

Clearly, this is an exciting time for those of us dedicated to preventing nicotine addiction and to helping those quit who have a desire to do so. The opportunities for dramatic improvements in public health and quality of life through the reduction of tobacco use are enormous, as long as there is a commitment to research-based action and trans-disciplinary interaction.

Thank you for the opportunity to speak and I am happy to answer any questions.

Senator FRIST. Dr. Leischow, the 14 years of age is the average age that adolescents begin or that people generally begin?

Mr. LEISCHOW. That people generally begin.

Senator FRIST. So a 14-year-old is the mean.

Mr. LEISCHOW. That is an important age in life.

Senator FRIST. Yes. And the mean and the median are basically the same?

Mr. LEISCHOW. I am sorry?

Senator FRIST. The mean and the median are the same?

Mr. LEISCHOW. That is the mean age, the average age.

[The prepared statement of Mr. Leischow follows:]

PREPARED STATEMENT OF SCOTT J. LEISCHOW

I. Background

Good afternoon. Mr. Chairman, and members of the Committee, I am grateful to have the opportunity to participate in this hearing on youth nicotine addiction. I am an Associate Professor of Health Education at the University of Arizona College of Medicine, as well as the Director of the Arizona Program for Nicotine and Tobacco Research. Our efforts are quite eclectic. We conduct clinical research that is funded by NIH and pharmaceutical companies to evaluate the safety and efficacy of new medications for smoking cessation and we have Arizona tobacco-tax funded internet based programs and services, a toll-free tobacco counseling service for the citizens of Arizona, and a tobacco education clearinghouse. Our activities range from prevention to treatment, and involve health care systems, schools, and worksites.

As we have heard, nicotine addiction is truly a pediatric disease that is both pervasive and profound. We see it daily at our center. But I know it personally as well. I am a former smoker who began at about age 13, and I was even suspended from

high school for smoking—which I should point out did not encourage me to quit. It has inspired me, however, to do my best to focus on what works and what does not so that cost effective strategies for reducing this major public health threat can be implemented.

2. Research

We know that 2/3 of those youth who experiment with tobacco do not become addicted, but the 1/3 who do become addicted represent about 1,000 new nicotine addicts per day. While we cannot accurately predict who will use or become dependent on nicotine, one very interesting pattern has begun to emerge from research.

Youth who are at greatest risk for developing nicotine dependence are also those who suffer from depression, anxiety and Attention Deficit Hyperactivity Disorder. Some researchers have speculated that youth who move beyond experimental use of tobacco may in effect be selftreating their psychological discomfort, since it is known that nicotine use can have a calming effect.

Speculation on the possibility of shared neurophysiologic pathways for depression, anxiety, Attention Deficit Hyperactivity Disorder, and tobacco use is supported in another way as well. The FDA has recently approved the use of bupropion—a non-nicotine medication that seems to enhance dopamine levels—as an effective smoking cessation treatment for adults, and it is now on the market. This same medication has been available for several years as an antidepressant. In addition, two studies have found that bupropion appears to be effective for the treatment of Attention Deficit Hyperactivity Disorder. The efficacy of this medication for several disorders that have been found to be clustered together with youth tobacco use reinforces the notion that there must be some common pathways—we just don't know for certain what those pathways are yet and only continued research effort can eventually answer that question.

Given this phenomenon, we have speculated that use of bupropion may very well be an effective smoking cessation treatment for youth as well. Through the support of the National Cancer Institute, we have just embarked on a study to evaluate the safety and efficacy of bupropion for that purpose.

Along with the funding from NCI, this study is also made possible because we have developed solid training, research, and service relationships with multiple managed care systems in Arizona as a result of Arizona's tobacco tax. This tax provides approximately \$30 million this year alone for tobacco education programs in Arizona—which has allowed the development of infrastructure relationships and transdisciplinary collaborations that make possible complex research and service programs that were not possible just a few years ago.

3. Future needs

Several areas of research warrant further exploration. Further exploration of psychiatric co-morbidities and factors that predict eventual tobacco use and dependence are essential in order to ultimately develop a full understanding of the mechanisms that control nicotine dependence.

Continued exploration of sociocultural factors that influence initiation and continuation of tobacco use is likewise necessary—particularly the impact of socioeconomic status, peers, advertising, tobacco cost, and social sanctions. For example, a study published just weeks ago found that even when vendors have been educated to avoid selling tobacco to youth, and then actually refrain from selling to youth, youth report no reduction in their ability to obtain tobacco. Thus, it appears that other strategies, such as increasing the cost of tobacco, may be more effective at decreasing use.

While we continue to explore biobehavioral mechanisms associated with tobacco initiation and dependence, tobacco use prevention and treatment research must move ahead. At present there is no consensus from the research community on what works for youth tobacco prevention and cessation. If research does not continue at an expanded pace, we run the risk as concerned parents, educators, clinicians, and policy makers to implement and entrench programs that have questionable validity. The National Cancer Institute is to be commended for taking a lead on research in this area, since they have recently funded 15 new grants to assess youth tobacco assessment, prevention, and treatment—and will fund additional research next year.

Just as we continue to pursue research, education, and policy initiatives dedicated to the reduction and eventual elimination of youth tobacco use, we can maximize on that effort by expanding our ability to develop interactive and collaborative systems for disseminating new knowledge. It is for that reason that our group has pushed ahead with internet-based technologies to expand interactions between schools, health care systems, nicotine and tobacco researchers—such as the Society for Research on Nicotine and Tobacco—and others interested in reducing tobacco use. More specifically, we have begun an NCI funded research project to use the web

to educate youth in schools about the risks of tobacco use and to even facilitate tobacco cessation efforts via the web page program and our toll free helpline.

Clearly this is an exciting time for those of us dedicated to preventing nicotine dependence and to helping those quit who have a desire to do so. The opportunities for dramatic improvements in public health and quality of life through the reduction of tobacco use are enormous—as long as there is a commitment to research-based action and transdisciplinary interaction.

Thank you for the opportunity to speak with you, and I am happy to answer as best I can any questions that the committee might have.

Senator FRIST. Dr. Hurt.

STATEMENT OF RICHARD D. HURT, M.D.

Dr. HURT. Good afternoon. I appreciate the opportunity to be here, as well, and with this group of really outstanding colleagues. As you have already mentioned, I am from the Mayo Clinic in Rochester, MN. I am a general internist who has an interest in addiction medicine. I want to describe a little bit about our program because it fits in with a lot of things that we are talking about.

I direct the Mayo Nicotine Dependence Center, which is a program based on the philosophical approaches of behavioral treatment, addictions treatment, pharmacologic treatment, and relapse prevention. It is an evidence-based clinical program with services that range all the way from individual counseling to inpatient treatment for people with very severe nicotine addiction and the services are primarily provided by masters-level counselors under the supervision of a physician.

Mayo, in general, provides clinical services in the context of an academic medical center, where education and research are essential to our mission. In fact, one of our more important activities at the Nicotine Dependence Center in the recent past has been to provide education experiences for other providers who have visited us and have gone back to their home medical institutions to develop programs which incorporate the concepts and approaches that we have found to be effective.

At our most recent training seminar, over 170 health care professionals from around the country were in attendance, including 80 from the U.S. armed services. We are continuing to assist many of these sites in the further development of their own clinical treatment programs using the technology that we have introduced them to.

As far as research is concerned, we believe that research and education are at the very foundation of all that we do and that the programs that we implement are evidence based with outcome data to ensure their value. Outcomes research is essential to this field at this particular time and will become even more important in the future as more funds become available for treatment and research services.

We have performed and reported in peer-reviewed literature outcomes studies on our basic clinical program, analysis of important factors in predicting those who stop smoking, outcomes in special populations, such as the elderly and patients with alcoholism and other addictions. We have assessed the outcome of our inpatient treatment program and most recently published a cost outcome study showing that our services are cost effective, which is very important in this day of healthy economies.

We believe, as Scott has mentioned already, that the pharmacologic therapy is and will continue to be a very important part of the treatment of people with nicotine addiction. An example of this is our paper that was published last week in the New England Journal of Medicine concerning bupropion, the first nonnicotine pharmacologic treatment to be proven to be effective in helping people to stop smoking.

We have also performed and published the only nicotine patch study in adolescents, and unfortunately, the results were quite disappointing. Those younger smokers have levels of nicotine addiction similar to adults, but the intervention that we did did not result in very many successes. Addiction to nicotine begins very early and most young smokers are addicted before they turn the age of 18. I think you heard already from the testimony today that many of them were addicted even well before that.

We have performed a second nicotine patch study in adolescents which has similar results, so we need to learn more about how to best treat young smokers. In our clinical program, we have treated over 250 young smokers over the last 4 years and we are presently assessing the outcome of their treatment and factors associated with successes.

Now, it has always been assumed that young smokers are not especially interested in stopping smoking. This really may no longer be the case. There are survey data showing that, like adults, most 16- and 17-year-old smokers want to stop. Furthermore, between the time that we did our first and second patch studies in adolescents, there has been a change in attitudes that we have seen. In the initial study, we had difficulty recruiting any young person to come in to be a part of the study, but in the present study, we had no difficulty at all recruiting over 100. In fact, we had a waiting list to get into the study. We need as a research community to capitalize on this change in attitude by providing effective behavioral and pharmacologic treatment.

For the future, for the general category of pharmacologic research, we need to continue to develop rigorous protocols to scientifically assess and aid in the development of products that may reach the public to ensure that they are effective, based on good science, and are then subjected to rigorous analyses, peer review, and finally, FDA scrutiny. We need to press forward with more intervention studies for adolescents, where very little work has been done to date, but also not neglect prevention.

The prevalence of smoking has already been stated. It has increased among adolescents in the past few years and the vast majority of the more than 3,000 new smokers each day come from those under the age of 18.

Now, most of the work has been done in prevention and there has not been a lot to show for that as yet. The AMA and the CDC are piloting an intervention program for student smokers in school-based health clinics. However, the most effective demonstration of reducing adolescent smoking has been in California and in Massachusetts, where a large cigarette tax increase was used to fund an extensive multimedia educational effort. Adolescents are quite price sensitive, but it has to be a substantial increase in the price.

Finally, we need to have a very serious educational effort for our health care providers and counselors to train them to provide intervention services in more medical centers throughout the country. This will also require credentialing of individuals so that they adhere to the same type of standards I have mentioned to you earlier. There are many potential counselors from a wide array of clinical disciplines who, with modest training, can provide effective services. We are quite excited about these new initiatives and look forward to using our skills in clinical medicine education research to help with this problem.

Senator FRIST. Thank you. Just a real quick question on your second study, where you said there was the influx of people coming in and it was much easier. Was your interpretation of that parental influence in getting them into the programs, or self-initiated?

Dr. HURT. No. I think it was mostly self-initiated and the kids just seemed to be more motivated to try to stop. Parental influence is not a small issue when it comes to doing adolescent studies involving a drug because you have to get permission from the parent or the guardian. So the first study we did, we had about 80 kids to call up and then only about 30 were able to show up for the first session because we told them on the telephone they had to bring their mom or dad or their guardian, so the rate of compliance went down a lot.

Senator FRIST. We will come back to that. Thanks.

[The prepared statement of Dr. Hurt follows:]

PREPARED STATEMENT OF RICHARD D. HURT, M.D.

I. Background

Good afternoon. I appreciate the time the subcommittee has spent on the very important issue of nicotine addiction. My name is Richard Hurt and I am a general internist, with a special interest in addiction medicine, and work at the Mayo Clinic in Rochester, Minnesota and direct the Mayo Nicotine Dependence Center. Our program is based on the philosophical approaches of behavioral treatments, addictions treatment, pharmacologic treatment, and relapse prevention. It is an evidence based clinical program with services that range from individual counseling to in-patient treatment where we hospitalize patients with severe nicotine dependence for the most intensive level of intervention available. The services are principally provided by master's level counselors under the supervision of a physician.

Mayo provides clinical services in the context of an academic medical center where education and research are essential to our mission. In fact, one of our more important initiatives at the Nicotine Dependence Center is providing educational experiences for other providers who have visited us and have gone back to their own medical centers and developed programs which incorporate concepts and approaches we have found to be effective. At our most recent training seminar over 170 healthcare professionals were in attendance, including about 80 from the U.S. military services. We are continuing to assist many of these sites in the further development of their treatment programs.

II. Research

We believe that research and education are at the very foundation of all we do and the programs that we implement are evidence based with outcome data to ensure their value. Outcomes research is essential to this field at this particular time and will be even more important in the future, as more funds are available for treatment and research services. We have performed and reported in peer reviewed literature, outcome studies on our basic clinical services, analyses of important factors in predicting those who stop smoking, and outcomes in special populations such as the elderly. We have assessed the outcome of our inpatient treatment program and most recently published in the October issue of the Mayo Clinic Proceedings, a cost outcome study of our clinical program showing our services to be very cost effective.

We believe that pharmacologic therapy is, and will continue to be, a very important part of the treatment of people with nicotine addiction. An example of this is our paper that was published in the New England Journal of Medicine last week

concerning bupropion, the first non-nicotine pharmacologic treatment to be proven to be effective in helping people to stop smoking. We have also performed and published the only nicotine patch study in adolescents to date and unfortunately the results were quite disappointing. Those younger smokers had levels of nicotine addiction similar to adults, but the intervention did not result in a substantial proportion who stopped smoking. Addiction to nicotine begins early and most young smokers are addicted before they turn 18. We have performed a second nicotine patch study in adolescents with similar preliminary results. So, we need to learn more about how to best treat young smokers. It has always been assumed that young smokers aren't especially interested in stopping smoking. This may no longer be the case as survey data show that like adults, most 16-17 year old smokers want to stop. Furthermore, between the time that we did our first and second adolescent patch study, there have been changes in the attitudes of the adolescents that we are seeing. In the initial study we had difficulty recruiting young smokers, but in the present study we had no difficulty recruiting over 100. We need to capitalize on this change in attitude by providing effective behavioral and pharmacologic treatment.

III. Future Needs

For the general category of pharmacologic research, we need to continue to develop rigorous protocols to scientifically assess and aid in the development of products that reach the public to insure that they are effective, based on good science, and are then subjected to rigorous analyses, peer review, and finally FDA scrutiny.

We need to press forward with more intervention studies for adolescents, where very little work has been done, but also not neglect prevention. The prevalence of smoking has increased among adolescents in the past few years, and the vast majority of the more than 3,000 new smokers each day come from those under the age of 18. Most of the work to date has been done toward prevention, and quite frankly there has been very little to show that our school-based programs for prevention have very much effect. The AMA and CDC are piloting an intervention program for student smokers in school-based health clinics. The most effective demonstration of reducing adolescent smoking has been in California and in Massachusetts where a large cigarette tax increase was used to fund an extensive multi-media educational effort. Adolescents are quite price sensitive, but it has to be a substantial increase in price.

Another high risk group of smokers which has received little attention are those with alcoholism and other addictions. We have performed one NIH funded study which shows that 50 percent of the mortality in previously treated alcoholics is from tobacco related diseases. We are presently starting an NIH funded study to provide pharmacologic/behavioral intervention for recovering alcoholic smokers. As with adolescents we need to advance the treatment technology for these patients.

Finally, we need a very serious educational effort for health care providers and counselors to provide intervention services in more medical centers throughout the country. This will also require credentialing of individuals so that they adhere to the same type of standards that I have discussed earlier. There are potential counselors from a wide array of clinical disciplines who, with modest training, can provide effective services.

We are very excited about the many initiatives that are underway. We have dedicated our clinical, educational and research efforts to the advancement of treatment services and the understanding of nicotine addiction. Through a concerted effort on the part of groups like the American Society of Addiction Medicine, the Society for Research on Nicotine and Tobacco, we believe that we can make great strides in the treatment of this very difficult addiction in both adolescents and adults.

Thank you for the opportunity to present, and I would be glad to answer any questions that you might have.

Senator FRIST. Dr. Fiore.

STATEMENT OF MICHAEL C. FIORE, M.D., M.P.H.

Dr. FIORE. Good afternoon, and thank you. I am Michael Fiore, a practicing physician and Director of the Center for Tobacco Research and Intervention at the University of Wisconsin. Recently, I served as Chair of the Agency for Health Care Policy and Research Clinical Practice Guideline on Smoking Cessation Panel. This panel of smoking cessation experts reviewed all of the research on nicotine addiction, and based on those findings, provided clinicians with evidence-based recommendations regarding quitting

successfully. In my view, this is a very successful example of an evidence-based practice approach to a major problem in America and I have provided a copy of the guideline to each of you.

The announcement of a possible global tobacco settlement has led many to hope that the enormous health and economic burden resulting from nicotine addiction may finally be eliminated. My remarks today will address a group I believe has been essentially excluded from these discussions, the 50 million Americans, both adults and children, currently addicted to tobacco. In my view, we have not focused sufficiently on providing effective clinical treatments to those Americans who already bear the health and economic costs of nicotine addiction. In essence, my remarks will urge us to not forget the smokers.

I would like to make three points. First, most smokers want to quit. Second, effective clinical treatments exist. And third, these effective treatments are underutilized by physicians and smokers alike.

In 1997, most smokers want to quit. The Office on Smoking and Health has documented these statistics on quitting. Among the 50 million current smokers in America, more than 70 percent have already tried unsuccessfully to quit and about one-third, almost 20 million, try to quit each year. Sadly, only about seven percent of those who try to quit succeed.

In my view, one of the reasons they are not successful is they have been not offered effective treatments, such as those identified in the AHCPR guideline. In fact, national statistics report that up to 90 percent of those trying to quit do so on their own, usually taking a "cold turkey" approach, and this, I believe, contributes to their low success rates.

I want to be clear in acknowledging that clinical treatment is not the only solution. Many of my public health colleagues have identified a variety of strategies to reduce tobacco addiction in our society, and appropriately, many of them have focused on preventing children and adolescents from ever becoming addicted. But I am struck by the under-emphasis on helping those already addicted to nicotine, and this includes adolescents as well as adults, and particularly those who are poor and less-educated.

This brings me to my second point, and that is new and effective treatments exist and these would have an enormous impact if implemented with every patient in every health care setting in America. As part of the AHCPR process, we reviewed all of the scientific research on quitting, what helps and what does not. The findings were striking.

First, clinicians can have a powerful impact in motivating their patients who smoke to quit.

Second, as little as 3 minutes of a physician's time can about double the rates of quitting among his or her patients, and the more time we spend, the higher the quit rates.

Third, one simple, essentially no-cost intervention, expanding the vital signs to include smoking status, markedly enhances the rates that physicians then go on to help their patients quit.

Fourth, every patient who tries to quit should be offered effective treatments, including social support, simple advice on how to quit successfully, and as mentioned by my colleagues, the

pharmacotherapies that have been demonstrated to increase the likelihood that a smoker will beat tobacco addiction, and these include the nicotine replacement therapies, the patch, the gum, the nasal spray inhaler, as well as the new nonnicotine medicine, Zyban.

Finally, to have the greatest impact, the whole health care delivery team, including insurers and managed care organizations, need to join in treating tobacco addiction. It is often difficult for physicians, given a discouraging paradox of the current reimbursement system. In virtually all instances, insurers pay for the very expensive outcomes of nicotine addiction, whether it be heart attack, a stroke, or cancer, but in only 50 percent of cases do they pay for the less-expensive smoking cessation counseling and medicines that would have prevented these illnesses.

Some have said, why provide smokers with treatment? Nothing works. I would propose that this statement is not supported by current research. Moreover, it appears to be based on a magic bullet standard, a demand that smoking cessation treatment guarantee a 50 or 70 or 90 percent success rate. This demand reflects a lack of understanding of the powerful nature of nicotine addiction.

When I talk to my physician colleagues, I urge them to change the way they think about nicotine addiction, to stop viewing it as an acute illness, like strep throat, that can be cured with a brief course of penicillin, rather to think about it for what it is, a chronic disease, similar to hypertension or hyperlipidemia or diabetes, with periods of relapse and remission as part of the disease.

While very similar to these other chronic diseases, nicotine addiction differs in one important respect. Three to five minutes of a physician's time combined with a two- to three-month course of medicine can lead 15 to 30 percent of patients each year into long-term remission off tobacco. There is not another chronic disease where physicians can have as powerful an impact with such a modest investment.

Think about the potential public health impact if clinicians nationwide provided the brief effective treatments outlined in the AHCPR guideline. The rate of quitting among those who try would increase from the background "cold turkey" rate of seven percent to at least 15 percent each year, and this would result in more than one million additional ex-smokers each year, ex-smokers who are healthier, who are more productive workers, and who utilize fewer health care resources.

In fact, we completed recently a cost-benefit analysis of implementing the AHCPR guideline and found that it was the most cost-effective adult preventive intervention in existence, only one-twentieth the cost of mammography.

The final point I would like to emphasize is that these effective treatments are terribly underutilized. While 70 percent of smokers see a physician every year, only about half are even urged by their clinicians to quit and less than 20 percent are provided with specific assistance on what will increase their likelihood of quitting successfully.

What can be done? I would suggest a number of specific steps. First, as part of any global settlement, sufficient resources to treat the majority of American smokers, both adults and children, who

want to quit should be provided. Since smokers will pay for this settlement, should not we be offering them effective treatments to help them to quit?

Second, establish an evidence-based guideline, such as the AHCPR guideline, as the standard of care for reimbursable smoking cessation treatment and update the guideline regularly.

We need to train clinicians to provide smoking cessation treatments. We need to designate research dollars to better understand the basic science of nicotine addiction, as well as research to identify effective treatments.

And finally, I believe we need to ensure that managed care organizations and other insurers take their appropriate role as partners in this effort, including the provision of effective smoking cessation treatments as covered services for patients who smoke.

I am convinced that we now have the potential to impact public health in a powerful way, in fact, to eliminate nicotine addiction and its devastating burden of illness, death, and cost from our society. In my view, we will only achieve this goal if we begin to focus more of our attention and more of our resources on the 50 million Americans already addicted to nicotine. Thank you.

Senator FRIST. Thank you, Dr. Fiore.

[The prepared statement of Dr. Fiore follows:]

PREPARED STATEMENT OF MICHAEL C. FIORE, M.D., MPH

Mr. Chairman and members of the committee, I am Michael C. Fiore, a physician trained in internal medicine and preventive medicine. I am an Associate Professor of Medicine and Director of the Center for Tobacco Research and Intervention at the University of Wisconsin Medical School in Madison, Wisconsin. Recently, I served as Chair of the Agency of Health Care Policy and Research (AHCPR) *Clinical Practice Guideline Panel on Smoking Cessation*. This panel of smoking cessation experts reviewed all of the research on nicotine addiction and, based on those findings, provided practicing physicians and other clinicians with evidence-based recommendations regarding what will help patients quit successfully.

The announcement of a possible global tobacco settlement has led many to hope that the enormous health and economic burden resulting from nicotine addiction may finally be eliminated. My remarks today will address a group that, I believe, has been essentially excluded from these discussions—the 50 million Americans currently addicted to tobacco. In my view, we have not sufficiently focused on providing effective clinical treatments to those Americans who already bear the health and economic costs of nicotine addiction. In essence my remarks will urge us to, “Not Forget the Smokers.”

I would like to make three points this afternoon—first, most smokers want to quit; second, effective clinical treatments exist; and, third, these effective treatments are underutilized by physicians and smokers alike.

In 1997, most smokers want to quit. The United States Office on Smoking and Health, Centers for Disease Control and Prevention, has documented the statistics regarding quitting in America. Among the approximately 50 million current smokers, more than 70 percent have already tried unsuccessfully to quit and about one-third, almost 20 million, try to quit each year.

Sadly, only about 7 percent of those who try to quit succeed. These tragic findings—most smokers wanting to quit while few beat nicotine addiction—has motivated me to devote my career to identifying effective clinical treatments for nicotine addiction.

In my view, one of the reasons that smokers are not successful is that they have not been offered effective treatments such as those identified by the AHCPR Smoking Cessation Clinical Practice Guideline. In fact, national statistics report that up to 90 percent of those trying to quit do so on their own, usually taking a “cold-turkey” approach. This contributes to their low success rates.

I want to be clear in acknowledging that clinical treatment is not the only solution. Many of my public health colleagues have identified a variety of strategies as part of a comprehensive approach to reduce tobacco addiction in our society. Appropriately, many of these strategies focus on preventing children and adolescents from

becoming addicted to nicotine. But, I am struck by the underemphasis on helping those already addicted to nicotine—and this includes both adolescents and adults, particularly those who are poor and less educated—groups experiencing some of the highest rates of smoking in our society.

This brings me to my second point—new and effective clinical treatments exist, and these would have an enormous impact if implemented with every patient in every health care setting in America. As—part of the AHCPR Smoking Cessation Clinical Practice Guideline process, we reviewed all of the scientific research on quitting—what helps and what doesn't. The findings were quite striking. First, clinicians have a powerful impact in motivating their patients who smoke to try to quit; second, as little as three minutes of a physician's time can about double the rate of quitting among his/her patients and the more time spent with smokers, the higher their quit rates; third, one simple, essentially no-cost, intervention—expanding the vital signs to include smoking status—markedly enhances the rate that physicians then go on to help their patients quit; fourth, every patient who tries to quit should be offered effective treatments including social support, simple advice on how to quit successfully, and pharmacotherapies that have been demonstrated to increase the likelihood that a smoker will beat tobacco addiction—nicotine replacement therapies (the patch, gum, nasal spray and inhaler) as well as the new non-nicotine medicine, Zyban. Finally, to have the greatest impact, the whole health care delivery team, including insurers and managed care organizations, need to join in treating tobacco addiction. It is often difficult for physicians given a discouraging paradox of the current reimbursement system—in virtually all instances, insurers pay for the very expensive outcomes of nicotine addiction—whether it be a heart attack or cancer or stroke—but, in only about 50 percent of cases, pay for the less expensive smoking cessation counseling and/or medications that would prevent those illnesses.

Some have said, "why provide smokers with treatment—nothing works!" I would propose that this statement is not supported by the current research findings. Moreover, it appears to be based on a "magic bullet" standard—a demand that smoking cessation treatments guarantee a 50 percent, or 70 percent, or 90 percent successful quit rate.

This demand reflects a lack of understanding of the powerful nature of nicotine addiction. When I talk to my physician colleagues, I urge them to change the way they think about nicotine addiction—to stop viewing it as an acute illness like a strep throat that can be cured with a brief course of penicillin. Rather, I urge them to think about it for what it is—a chronic disease similar to hypertension, or hyperlipidemia, or diabetes with periods of relapse and remission as part of the disease. This requires primary care physicians to treat patients over time and frequently, try a series of interventions. While very similar to other chronic diseases, nicotine addiction differs in one important respect—three to five minutes of a physician's time combined with a two to three month course of nicotine replacement therapy or Zyban can lead 15 percent to 30 percent of patients each year into long term remission off tobacco. There is not another chronic disease where physicians can have such a powerful impact with such a modest investment.

Think about the potential public health impact if clinicians nationwide provided the brief, effective treatments outlined in the AHCPR Guidelines. The rates of quitting among those who try would increase from the background, "cold-turkey" rate of 7 percent to at least 15 percent each year.

This would result in more than *one million* additional ex-smokers per year—ex-smokers who are healthier, who are more productive workers, and who utilize fewer health care resources. In fact, we recently completed a cost-benefit analysis of implementing the AHCPR Smoking Cessation Guideline nationwide and found that smoking cessation was the most cost effective adult prevention intervention—one-twentieth the cost of mammography screening. These results will be reported in December in the *Journal of the American Medical Association*.

The final point I would like to emphasize is that these effective treatments—both counseling and medications—are terribly underutilized. While 70 percent of smokers see a physician each year, only about half are urged to quit by their clinician and less than 20 percent are provided with specific assistance—counseling and medications—that can increase the likelihood they will successfully quit.

What can be done? I would suggest a number of specific steps:

- 1) Include as part of any global settlement sufficient resources to treat the majority of American smokers who want to quit. Since smokers will pay for the settlement, shouldn't we offer them effective treatments to help them quit?
- 2) Establish an updated, evidence-based Guideline, such as the AHCPR Guideline, as the standard of care for reimbursable smoking cessation treatment.
- 3) Train clinicians to provide effective smoking cessation treatment.

4) Regularly update the AHCPR Smoking Cessation Guideline to provide clinicians with the most current, effective treatments.

5) Designate research dollars to better understand the basic science of nicotine addiction as well as applied research to identify effective treatments to help people quit.

6) Ensure that managed care organizations and other insurers take their appropriate role as partners in this effort including the provision of smoking cessation treatment (both counseling and pharmacotherapy) as a covered service for patients who smoke.

I am convinced that we now have the potential to impact public health in a powerful way—to eliminate nicotine addiction and its devastating burden of illness, death, and economic cost from our society. In my view, we will only achieve this goal if we begin to focus more of our attention, more of our resources, on the 50 million Americans already addicted to nicotine.

Thank you very much.

Senator FRIST. Dr. McAfee.

STATEMENT OF TIM McAFEE, M.D., M.P.H.

Dr. McAFEE. Good afternoon, Mr. Chairman and committee members. I appreciate the opportunity to testify today. My name is Dr. Tim McAfee and I am here today representing Group Health Cooperative of Puget Sound, the Nation's largest consumer-governed health maintenance organization, with 650,000 enrollees. Group Health is also affiliated with Kaiser-Permanente, a national nonprofit managed care organization with nine million members.

I will be speaking about what we have learned regarding the impact of providing medical coverage for smoking cessation services from three perspectives I know intimately, as a family physician, as the Director of our Center for Health Promotion, which seeks to proactively improve the health of our members, and as the Director of Free and Clear, our highly successful smoking cessation program.

There are three main take-home messages I will be emphasizing. First, providing coverage and removing access barriers for proven methods that help patients quit smoking dramatically increases participation without compromising success.

Second, cessation services are the health care bargain of the millennium.

And third, easy access to proven methods that help to quit smoking is an important smoker's right, and is important if we want to decrease youth initiation smoking, as well.

Ten years ago, Group Health took part in a National Cancer Institute clinical trial, using an inexpensive smoking cessation program called "Free and Clear" that can be used either in a traditional class or over the phone. The study found that participation doubled the person's chances of successfully quitting and staying off tobacco over a year later.

In 1992, we took a hard look at what we had done with this information and discovered that only 180 smokers a year were using this proven service. We worked hard to understand why, since smoking is the number one cause of preventable death in our population. By making a few relatively simple changes, we increased participation in this program 15-fold.

First, we made the Free and Clear program available over the phone and then experimented with removing financial barriers. We found that allowing smokers to quit at their own pace with telephone or group support from a trained specialist and with access

to aids, such as nicotine patches, boosted participation from one in 200 smokers per year to one in 15, with almost a tripling of individual one-year success rates over a baseline, from ten percent to 30 percent. We are expecting about 3,000 Group Health smokers to use the Free and Clear program in 1997.

What does it cost us to provide this service? About \$220 per participant, including both telephone or group support and nicotine patches. At that price, 1,000 people successfully quit smoking for less than the cost of lung transplants for two people with smoking-related lung disease. Plus, we add at least 3 years of life expectancy to each of these smokers who quit and we do not really yet know how much life expectancy is added to the lung transplant recipient, probably less than 3 years.

In addition to providing the Free and Clear program to our members, we also provide it on a fee-for-service basis, mostly to members of other health plans and employer groups. Our experience in this area has reinforced our experience with our own enrollees. That is, we get lousy participation when financial barriers are placed in the way.

As a family physician, I believe that easy, free access to smoking cessation support is an important, neglected smoker's right. About 70 percent of smokers, as Dr. Fiore said, hope to quit in the next 6 months, but only about seven percent or less will be successful because nicotine is addictive. We know there are relatively cheap proven methods, such as counseling programs and drugs and physician advice that definitely can help smokers quit. Our experience at Group Health shows that by removing financial and geographic barriers, we can dramatically increase participation in these programs.

As cigarette taxes and tobacco settlement dollars increasingly provide support for general social and health care programs, it is morally imperative that we use a portion of this money to ensure that motivated tobacco users have easy access to proven help for quitting. Payment is a barrier.

I remember a Medicaid patient of mine last year, a young woman who was pregnant and who continued to smoke during her pregnancy but desperately wanted to quit. She tried and tried on her own, unsuccessfully. She wanted to enter our Free and Clear program but could not pay for it. At that time, Medicaid patients, who have a smoking rate twice that of the general population and for whom payment is an even bigger barrier, were one of the few Group Health members for whom smoking cessation was not covered because State and Federal Government do not include it as part of the benefit package.

Pregnancy is perhaps the area where coverage barriers are the hardest to justify or understand, because they penalize the unborn child and we make back our investment by the end of the pregnancy by avoiding low birth weight babies that cost us tens of thousands of dollars.

Fortunately, Group Health has decided not to wait for government action and now provides 100 percent coverage for all smokers, including Medicaid. Since doing this, we have had over a ten-fold increase in participation by our Medicaid members.

A potential concern about funding these programs is it may decrease funding for programs aimed at keeping kids from starting to smoke. Two responses. First, there is the situation of a Group Health member who just enrolled in the Free and Clear program last week. He has a 2-year-old daughter and an 11-year-old son. His successfully quitting is far and away the best thing that can happen, as Josh said earlier, in terms of keeping his two children from starting to smoke, because children of smokers are twice as likely to start smoking as children of nonsmokers. By helping him successfully quit, we are helping his kids.

Second, providing quitting assistance for motivated smokers should be a built-in cost of doing business for the tobacco industry, period. It should not compete with funds to discourage kids from taking up smoking or any other public health or medical efforts.

In conclusion, providing coverage and removing access barriers for proven methods that help quit smoking increases participation. Cessation services are a health care bargain which we should be maximizing. And finally, easy access to help when quitting smoking is an important smoker's right that is also important if we want to decrease youth initiation of smoking. Thank you very much.

[The prepared statement of Dr. McAfee follows:]

PREPARED STATEMENT OF TIM MCAFEE, MD, MPH

Good afternoon Mr. Chairman and committee members. I appreciate the opportunity to testify today. My name is Dr. Tim McAfee, and I am here today representing Group Health Cooperative of Puget Sound, the Nation's largest consumer-governed health maintenance organization, with 650,000 enrollees. Group Health is affiliated with Kaiser-Permanente, the largest and oldest national non-profit managed care organization with 9 million members. I am speaking about what we have learned about the impact of providing medical coverage for smoking cessation services from three perspectives I know intimately: as a family physician, as the director of our Center for Health Promotion, which seeks to proactively improve the health of our members, and as the director of our Free & Clear program, one of the most successful smoking cessation programs in the country.

There are three main take-home messages I will be emphasizing: First, providing coverage and removing access barriers for proven methods that help patients quit smoking dramatically increases patient participation without compromising success,

Second, cessation services are the healthcare bargain of the millennium, and

Third, easy access to proven methods that help to quit smoking is an important "smoker's right" and are important if we want to decrease youth initiation of smoking.

Ten years ago, Group Health took part in a National Cancer Institute clinical trial using an inexpensive smoking cessation program called "Free & Clear" that can be taken either in a traditional class or over the phone. The study found that participation doubled a person's chances of successfully quitting and staying off tobacco over a year later.¹ In 1992, we took a hard look at what we had done with this information, and discovered that only 180 smokers a year were using this proven service. We worked hard to understand why, because we had decided that decreasing smoking in our population was our number one prevention priority, since it is the number one cause of preventable death. What we have discovered is that by making a few relatively simple changes, we could increase participation 15-fold! First, we made the Free & Clear program available over the telephone, then we experimented with removing financial barriers to participation. We found that allowing smokers to quit at their own pace with telephone or group support from a trained specialist and with access to aides such as nicotine patches, boosted participation from one in 200 smokers per year to one in 15, with almost a tripling of individual one-year

¹ Orleans CT, Schoenbach VJ, Wagner E, et al. Self-help quit smoking interventions: effects of self-help materials, social support instructions and telephone counseling. J Consult Clin Psychol 59: 439-448, 1991.

success rates over baseline, from 10 percent to 30 percent. We are expecting almost 3,000 Group Health smokers to use the Free & Clear program in 1997.

What does it cost us to provide this service? About \$220 per participant, including both telephone or group support and nicotine patches. At that price, 1,000 people successfully quit smoking for less than the cost of lung transplants for two people with smoking-related lung disease. Plus, we add at least three years of life expectancy to each of the smokers who quit smoking. We do not yet know how much life expectancy is added to the lung transplant recipient. It is unlikely to exceed three years.

In addition to providing the Free & Clear program to our own members, we have also provided it on a fee-for-service basis since 1989. About 85 percent of Free & Clear services are provided to other health plans and employer groups nationwide. Our experience in this arena has reinforced our experience with our own enrollees; that is, we get minimal participation when financial barriers such as large co-pays or out of pocket expenses for patches or gum are placed in the way.

As a family physician, I believe that easy, free access to smoking cessation support is an important, neglected, smoker's right. We know from countless polls that about 70 percent of smokers hope to quit in the next six months. But we also know that only a small fraction will be successful in their attempts, because nicotine is addictive. We know there are relatively cheap, proven methods such as counseling programs and drugs that definitely help smokers quit. Our experience at Group Health shows that by removing financial and geographic barriers, we can dramatically increase participation in these programs. As cigarette taxes and tobacco settlement dollars increasingly provide support for social and healthcare programs, it is morally imperative for us as a society to use a portion of this money to ensure that motivated tobacco users have easy access to proven help for quitting. It is imperative, because we know that, in fact, payment is a barrier. I remember a Medicaid patient of mine last year, a young woman who was pregnant and who continued to smoke during her pregnancy but desperately wanted to quit. She tried and tried on her own unsuccessfully. She wanted to enter the Free & Clear program, but couldn't pay for it. At that time, Medicaid patients, who have a smoking rate twice that of the general population and for whom payment is an even bigger barrier, were one of the few types of Group Health members for whom smoking programs were not covered (because the state and federal government do not include it as part of the benefit package). Pregnancy is perhaps the area where coverage barriers are the hardest to justify, because they penalize the unborn child, and we make back our investment by the end of the pregnancy, by avoiding low-birthweight babies that cost tens of thousands of dollars in medical expenses. Fortunately, Group Health has decided not to wait for governmental action, and now provides 100 percent coverage for all smokers, including Medicaid. Since doing this, we have had over a 10-fold increase in participation by Medicaid members.

Similarly, our experience with Medicare has been that very few people enroll if they have to pay. In the first five months of 1997, before we removed the copay barrier, we had one medicare participant. Since then we have had over 110.

Overall, our populations smoking rate has fallen from 25 percent to 15 percent over the past decade, while Washington State went from 25 percent to 23 percent. We think this large drop is at least in part due our systematic efforts to address tobacco use with the same level of seriousness that we address other serious medical conditions, including education of physicians and nurses, measurement of key performance indicators such as appropriate charting and patient exit interviews, and provision of covered cessation services.²

A potential concern about funding these programs is that it may decrease funding for programs aimed at keeping kids from starting to smoke. I have two responses. First, there is the situation of a Group Health patient who just enrolled in the Free & Clear program last week. He has a two-year-old daughter and an 11-year-old son. He smokes. He is trying to quit. His successful quitting is far and away the best thing that can happen in terms of keeping his two children from starting to smoke, because children of smokers are twice as likely to start smoking as children of non-smokers. By helping him successfully quit, we are helping his kids. Second, providing quitting assistance for motivated smokers should be a built-in cost of doing business for the tobacco industry. Period. It should not compete with funds to discourage kids from taking up smoking, or any other public health or medical effort.³

In conclusion:

² McAfee T, Wilson J, Dacey S. Awakening the sleeping giant: Mainstreaming efforts to decrease tobacco use in an HMO. *HMO Pract* 1995; 9: 138-46.

³ Wagner, EH et al. The impact of smoking and quitting on health care use. *Arch Int Med* 1995; 155: 1789-95.

- Providing coverage and removing access barriers for proven methods that help quit smoking dramatically increases participation without compromising success,
 - Cessation services are a healthcare bargain whose use should be maximized,
 - Easy access to proven methods that help quit smoking is an important "smoker's right", that is also important if we want to decrease youth initiation of smoking.
- Thank you for inviting me to speak with you today.

Answers to Some Additional Questions

If we pay for services to help smokers quit, won't that take away from the most important issue, keeping kids from starting?

We already are paying hundreds of billions of dollars to treat smoking-related disease. These treatments are all covered by insurance plans

More details re: effect of coverage on participation?

In 1992 we had 180 participants a year. By making a telephonic version available and removing all but a \$42 copay, we boosted participation to 1,500 a year. This year we removed the \$42 copay, and participation is jumping to 2,500 a year.

We also have done a study of the effect of different copays on participation, with 11 percent of smokers participating with no coverage barrier, but only 3-5 percent with large copay barriers in place.

In our fee-for-service business, we have discovered that a financial barrier as low as \$50 has dramatically decreased participation. For example, two national employer group with about 100,000 employees each, offered our program but with no coverage. They had zero participants. Another national company with 110,000 offered the program with no program copay and only \$10 for nicotine replacement therapy, and had 3,200 participants the first year.

More details re: cost-effectiveness of programs?

Cost-effectiveness estimates are in the \$500 to \$2,000 per year of life saved for organized programs. Brief physician intervention costs more—about \$6,000 per year of life saved. However, all these interventions compare very favorably to other medical and screening interventions such as cholesterol lowering, mammography, and pap screening that cost tens of thousands of dollars per year of life saved.

Why should we pay for these services when most people are not successful, even when they use a program???

Taking part in an organized program and using pharmacological treatment such as nicotine patches or the new drug bupropion doubles or triples the chance of success. In Group Health's program, we estimate that we treat five people to successfully get one person to quit permanently. That person adds 3-7 years to their life expectancy. In fact, this is a much better rate than most medical or prevention treatments. Lifetime use of blood pressure or cholesterol lowering medication requires treating over 50 people to benefit one, and is much more expensive. Providing mammography in women 40-49, which costs much more than smoking cessation, requires at least 2,500 women to participate for an entire decade to avoid one breast cancer death.

What is currently going on in health plans?

A 1995 survey of 105 large HMOs found that 2/3 offer some level of smoking cessation program. However, these often include large copays, reimbursement at the end of treatment rather than initially, and sometimes requirements that a person be smoke-free to be reimbursed. Provision of services tends to be better in staff and group model plans than network or IPA models (which now predominate in managed care).

Medicaid programs reimburse for programs in only five states. 17 reimburse for prescription nicotine replacement therapy. Medicare does not reimburse at all.

What about youth cessation programs—do they work???

No program has yet been developed and evaluated that has successfully increased cessation rates in youth. Further study is needed. As with adults, many adolescents want to quit, and have tried unsuccessfully.

How can we avoid creating a new industry with very expensive programs if money is channeled more easily to smoking cessation programs or drug treatment, such as has happened to some extent with alcohol and drug treatment?

This is a legitimate concern. It is reasonable to link drug coverage to participation in behavioral follow-up to ensure better cessation rates, as long as barriers to access to the follow-up are removed. There is not data to support that very expensive interventions such as hospitalization or very intense follow-up is superior to the more modest programs currently in existence. It would be better public policy to limit reimbursement to the \$200-300 range than to require copays.

Who should pay? Health plans, the government through taxation, the tobacco industry, or individual smokers?

Health plans are widely variable in their coverage practices. Smoking cessation is frequently seen as an optional health education service, not as a medical service. Health plans do recoup the money they spend on smoking cessation services within four years due to decreases in hospitalization, as evidenced by a study conducted at Group Health that compared costs between a large group of smokers who quit compared to those who didn't. But the current healthcare industry environment only rewards changes that result in clear savings within six to twelve months. Many health plans sincerely want to do a better job, as evidenced by their support for an NCQA/HEDIS measure on physician advice to quit. However, health plans are worried that coverage may lead to enormous increases in pharmacy costs. Although this fear is overblown as our experience shows, there are significant costs associated with providing coverage (we estimate it costs us about twelve cents per member per month to fully cover smoking cessation services).

The governmental agencies responsible for insuring large populations have generally been reluctant to cover cessation services, even when it involves low-income people such as medicaid or medicare who need it the most. In general, there has not been much pressure from public health agencies to change these policies, partly due to concern that scarce public health resources should be spent on tobacco prevention programs, and in public education campaigns, rather than on the delivery of clinical services. Within the healthcare arena there has been concern that covering cessation services could set a precedent for coverage in other health education areas.

It seems at first glance to be logical to require smokers to pay for cessation services, since they are "choosing" to smoke. There are several problems with this approach. First, we do not require smokers to pay for other consequences of smoking that cost many billions of dollars more than cessation services, such as cardiac surgery, diabetic complications, and medications for treatment of lung diseases. Second, many adult smokers are not freely choosing to continue smoking: they are addicted, and want to stop but have been unable to. Third, the reality is that requiring payment is a major barrier to smokers using cessation services.

The most logical candidate to pay for cessation services is the tobacco industry. Determining some mechanism by which cessation service coverage is a built-in cost of doing business for the tobacco industry makes the most sense from a public policy and business sense.

Senator FRIST. Thank you, Dr. McAfee.

Dr. Hurt, could you explain for our committee members in physiologic terms how nicotine interacts with the body? All of you have said and underscored the addictive aspects of nicotine. Just to start off our discussions, could you tell us what nicotine does?

Dr. HURT. Well, first of all, it depends on the delivery system, and that is something that Jack Henningfield from NIIDA has shown, that the delivery system itself has a lot to do with the addictive potential of the drug. The cigarette is the most efficient delivery system of nicotine that exists.

The physiology of it is, you smoke it, it goes into the lungs, it is pumped to the left side of the heart, and within five heartbeats, it goes from here to here. You put a patch on your arm, it goes into the venous circulation, gets mixed in with all the total blood volume, goes to the right side of the heart, pumped to the lungs and into the left side of heart. So the venous levels and the arterial levels coming from a nicotine patch are basically the same. When you smoke something, the arterial levels may be three to six or seven times higher in the central nervous system than they are in the venous system.

So first of all, the delivery form is very, very important, and what it does to the nicotine receptors that are present in the brain is part of the addictive process. There is a process called up-regulation that occurs within these very high levels in the brain that makes more of these receptors available, and then when the nico-

tine is not present in the system, then those same receptors which have been sensitized then say, well, where is the nicotine, and therein is the craving, the urges to smoke, and so on.

So it really is a biochemical problem mediated through these very high levels of nicotine achieved with arterial levels of nicotine achieved from smoking and then the receptors and the neurotransmitters that come out on the other side, like dopamine, which has been mentioned already, and there are several neurotransmitters that are involved in that process.

We are just beginning to understand this as a scientific community and much of that has been led by the work that we have done in the pharmacology of it.

Senator FRIST. Are there any other comments to add while we are talking about the addictive aspects of nicotine, in terms of basic explanation? [No response.]

Again, this question will be for the whole panel but addressed to Dr. Hurt. Is there a difference in what you just described about addiction between adolescents, and those of middle age 40 or 50 years old?

Dr. HURT. Well, it depends on when the person starts using, and I do not know that anyone has teased out the differences in adolescent receptors in the brain compared to a person my age, in their 50s, that might try to start smoking at that age.

The facts are that most people who are adult smokers began before the age of 18, and actually, most of them began before the age of 16. So they are exposed to these very high levels of nicotine that do things at the receptor level in the brain and become addicted fairly quickly.

For example, in the study we did in the adolescents we had, they looked basically like adults did as far as the scores that you give for addiction levels, but they had more difficulty stopping with the traditional methods than their adult counterparts. And the other thing that was just mentioned in that study, over 70 percent of the kids in that study were from households where there were other smokers. It is a big risk factor. So by helping the whole spectrum of smokers, we will indirectly help those kids who, if not exposed to that in their home, might never start to begin with it.

Senator FRIST. So physiologically, we think the addiction cycle is similar in young and old. Your nicotine patch study showed pretty clearly that using nicotine patch as a cessation tool in this young population does not work as well as with adults. What are the reasons for that?

Dr. HURT. We do not know, and we are trying to learn more from the second patch study and we are actually going to propose to do another pharmacologic treatment in adolescents. We work with these kids in our clinical program and try to individualize the treatment, but as far as studies, there are very few intervention studies in adolescent smokers. We are just at the beginning of the beginning to learn how to help them.

The assumption has always been that the kids did not really want to stop, and I think that is a bad assumption. I think we just have not reached out to them. All the intervention trials have been for age 18 or older and part of that is because of parental consent and guardian consent and so on, but we have neglected this area

for these younger smokers. We just do not know as much about it as we should.

Senator FRIST. I think that speaks very loud and clear to the need, especially if we are going to be making policy or cessation in the critical adolescent group, that we at least understand why cessation programs do not work as well in that group, or whether we have to approach this group differently, as I think your studies show.

Dr. Leischow, would you comment a little further on this whole concept of self-medicating for anxiety, for depression. We know adolescents have different needs, psychological needs. They are going through the various growth processes of adolescence. You mentioned anxiety, depression, attention deficit disorder in this group. Of teen smokers, is there data, on what percentage of adolescents fall into this self-medicating category out of this large population of teen smokers?

Mr. LEISCHOW. Yes. I can get you the actual studies, but it is probably in the neighborhood of 10 to 20 percent, somewhere in that range.

Senator FRIST. So it is substantial.

Mr. LEISCHOW. And we know that kids who become dependent, we know that kids who become dependent are much more likely to suffer from one of those disorders.

Senator FRIST. When you say 20 percent, that is for the adolescent population, roughly?

Mr. LEISCHOW. Yes, who initiate—

Senator FRIST. What percentage of the entire adult population falls into this self-medicating category?

Mr. LEISCHOW. I do not know. I do not know.

Senator FRIST. Do teens who smoke for social reasons have as much difficulty quitting as those who fall into this category of self-medicating?

Mr. LEISCHOW. Well, I guess I should say that we do not really know for sure which kids are self-medicating and which ones are not. It is still speculation at this point. But I think the critical issue is that the likelihood of quitting is, in large measure, a function of the amount that a person smokes. So if a youth uses nicotine to the same degree as an adult, they are going to have a similar difficulty of quitting, regardless of what the mechanisms are for why they started.

I think we need to really focus on several different parts of the continuum, both why do people initially use, you know, and the social pressures associated with that. What affects continuation, and then what affects actual addiction? Those parts are intermixed in ways that we do not really understand, and, hence, the need for more research to tease that phenomenon out. We just do not know what is going on and why.

Senator FRIST. Thank you.

Senator DeWine.

Senator DEWINE. Mr. Chairman, thank you very much.

Dr. Hurt, let me read from your testimony and ask you and perhaps the other members of the panel, maybe, to comment on this. "The most effective demonstration of reducing adolescent smoking rates has been in California and in Massachusetts, where a large

cigarette tax increase was used to fund an extensive multimedia educational effort. Adolescents are quite price sensitive, but it has to be a substantial increase in price. The combination of higher prices and such an educational campaign can reduce the number of adolescent smokers who begin to smoke." I want to ask for the other members of the panel if they have any comments on that statement.

Dr. FIORE. I would like to comment on it. That is well supported by data. The United States Office on Smoking and Health over the last 30 years has tracked rates of cigarette consumption and has found clear declines in that consumption every time the Federal excise tax is increased and the degree to which it has declined has been quite substantial when there was an increase of ten cents or more, in the range of ten cents or more. We also know this from the experience of the Canadian government when they implemented a very large increase in their excise tax, now, I think, more than a decade ago.

So that is well supported by the data, as well as, as Dr. Hurt has mentioned, the specific experience of California and Massachusetts, who have been a success in what has been otherwise a national failure over the last five to 10 years to prevent young people from starting to smoke.

Senator DEWINE. Excuse me, if I could just follow that up. A hearing that I am going to be chairing on Wednesday is going to get into this in a little bit more detail, but the drop in consumption that occurs with the increase in price, the inverse relationship, is there a flip-back to that, though? In other words, at some point, do the levels just go back to where they were? I mean, is there a stick-er shock? Is there, yes, people are affected for a few months, but then, well, that just becomes what we pay for a pack of cigarettes, just like that is what we pay for a car or something else?

Dr. FIORE. Well, if you take California and Massachusetts as two examples, that has not been the case. California has continued to have lower Statewide smoking rates in all groups compared to the Nation as a whole and the beginning of that process was around the time of the 25-cent Proposition 99 initiative.

Senator DEWINE. But the levels, to make sure I understand, the level we are talking about is how much of an increase in these two cases, California and Massachusetts?

Dr. FIORE. It was 25 cents in California, and was Massachusetts the same?

Dr. HURT. It was more than that. Actually, Massachusetts just added another quarter on top of that last increase.

Senator DEWINE. Any of you can jump in here.

Mr. LEISCHOW. I should point out, Arizona has a tobacco tax, as well, that was implemented 2 years ago, and that is 40 cents a pack in addition to what was there already, and we have, likewise, seen decreases in tobacco use.

Dr. HURT. So in California, if you look at it over time, the smoking rate in California is probably the lowest of any State in the country, with the possible exception of Utah, and there are obvious reasons for that. I would ask you to look at the excise tax rates in our country compared to the excise tax rates in all other Western countries and I think you will find that our tax rate is relatively

low, and, in fact, adjusted for inflation, cigarettes may be cheaper now than they were when I used to smoke.

Dr. MCAFEE. I would just like to add, coming from the State of Washington, which actually has, I think now, the highest or one of the highest cigarette taxes, a small caveat that I think is important, and that is that most of the places that have done this have not just done a cigarette price increase. They have also implemented well-funded programs that aim both at increasing media counter-advertising and also improving funding for school-based programs. Those two interventions have been well studied by Brian Flynn in an actual randomized community trial and have shown to be quite successful at decreasing youth initiation.

In the State of Washington, we increased our cigarette tax without providing any money to school programs or media programs and have not seen the types of drops that have been seen in these other States. So I think we need to proceed cautiously with the idea, as I think you were suggesting, that simply raising cigarette taxes by ten or 20 cent is a permanent solution. The Canadian taxes were enormous. They were dollars, not ten or 20 cents.

I think the other side that we need to do is a much profounder level of ongoing funding from tobacco, either through the settlement and/or taxation for the programs that have been shown to work to decrease youth initiation, and we also need to do more research to try to find other programs that may also work.

Dr. HURT. So I think the examples in front of us are probably three. The oldest example is in California. The next oldest is in Massachusetts, and Tim is exactly right. What I said in my testimony was that it takes both a tax increase plus the multimedia as well as other efforts, because it is not just the tax increase. The newest evidence will be coming from Arizona, I would suspect, in a few years.

Senator DEWINE. To summarize, three things, price, number one—in no particular order, but price, a school-based program or prevention-type program, whether it is school-based or otherwise, and a media, anti-smoking media. Is that the summary?

Dr. MCAFEE. And then we need further research.

Mr. LEISCHOW. Cessation, as well.

Dr. MCAFEE. Well, we need further research in the realm both of what we can do in the clinical arena, both around primary prevention and in the cessation arena. For instance, we are going to be doing a randomized trial NCI funded at Group Health where we look at a combination of a clinical intervention for 11-year-olds combined with a parental outreach education to parents around how to help their kids keep from smoking. But these are things that are going to take years to get answers to.

Senator DEWINE. Summarize for me, if you could, the one component that we just listed, and that is prevention. What do we know? What do we know works? Where are we with that? I know several of you have touched on that in your testimony already, but I wonder if you could just summarize that for me.

Dr. HURT. I think that the evidence for school-based prevention programs is lacking as far as showing efficacy. I think we have to go beyond that, and I would go back to the experience in California. I serve on one of the study sections for the research dollars from

there and know that they have not only research dollars but they also have this very large health media education effort, as well.

So it is not just, I think, school-based programs. We may even need to think about school-based programs like we do for other chemical dependencies, maybe as a place to identify kids who are smokers, maybe intercept them earlier in the process before they become heavily addicted, counsel them, refer them on for more treatments. I think school-based prevention programs in the traditional sense have not been shown to be effective in preventing youth start-ups.

Mr. LEISCHOW. Probably the best we have achieved so far is delaying the onset, and we really have not achieved true prevention at this point. I mean, certainly, delaying onset is an important outcome, or at least an initial important outcome, but that is certainly a long way from where we need to go.

Dr. FIORE. There is research, though, apart from the school-based programs, as to what appears to help in preventing kids from starting to smoke and we have touched upon, I think, all of them today. Increase the cost, ban advertising, and particularly dedicate resources to counter-advertising, deal with youth access. The panel earlier shared with us the way, as it is in virtually every community in America, the kids know where they can buy their cigarettes and they buy those cigarettes with impunity. And last, develop and enforce clean indoor air laws that denormalize smoking.

Those four strategies, cost, advertising and counter-advertising, youth access, and clean indoor air, each have been shown in certain ways to be helpful in preventing children. I think what all of us on this panel want to add to that and to not lose sight of is helping those already addicted to successfully quit, both for themselves as well as the fact that they become a conduit—adults who smoke become a conduit to children smoking themselves.

Senator DEWINE. Let me just, if I could, conclude. I think your comments are very pertinent and very helpful. This Congress, and more importantly, this country has, I think, a unique opportunity, a historic opportunity. Because of the proposed tobacco settlement, we have an opportunity to weigh in and to do something that we hope will be very meaningful in regard to the reduction of teenage smoking. Whether we as a country step up to that opportunity or not, it frankly remains to be seen.

If we do go ahead and pass a comprehensive bill which incorporates portions of the tobacco settlement and maybe goes beyond that tobacco settlement or changes it in some way, the decisions that we are going to have to make are directly related to some of the questions I have been asking you. What works and what does not work? If resources are put in one area, they may not be put in another area, or they may not be put in another as extensively.

So the Congress is going to have a choice and the American people are going to have a choice of where the resources are going to be put. We are going to have to look at the issue of how much is enough for the tobacco price to go up. What will actually make a difference? What will have an impact, and what else has to be done along with that increase in tobacco?

It seems to me that your testimony, collectively, makes a great deal of sense to me, that there are three, four, maybe five different

things as a country we are going to have to do, and some of them, frankly, we are not going to know what is going to be effective. When you get into the whole area of prevention, I have had some experience in a previous life as a Lieutenant Governor of the State of Ohio and then before that as a Congressman in looking at the whole issue of prevention in regard to drugs, drugs and alcohol. Quite frankly, it is difficult to get good data about what works and what does not work, and I suspect when we are dealing with tobacco, it is not really dissimilar to that problem and that challenge.

But it does not mean that you do not anything and it does not mean you hide your head in the sand and you forget about trying to do prevention. So I think we have to move ahead, and as you point out, have to have research, additional research to determine what is effective and what is maybe not quite so effective.

Mr. LEISCHOW. One of the considerations to think about is that tobacco use, in some respects, is like a communicable disease. We could try to prevent it, but if we continue to have large numbers of people continue to smoke, that will certainly affect those that we are trying to prevent, or those people that we are trying to prevent using tobacco. So a comprehensive approach is really the key.

Senator DEWINE. Mr. Chairman, thank you.

Senator FRIST. Thank you.

I have a couple of other questions, and then I want to move to the third panel. Going back to smoking cessation, which ties in with the conversation we just had, we have discussed prevention, which we are concentrating on, but the other aspect is cessation. Is there any youth cessation program that works that we have data on? I know that one danger we face as policy makers is to come out promoting programs, throwing money at programs and hoping that they will work because, intuitively, they make sense. Are there smoking cessation programs for adolescents, which is where the problem is? Can you give me data or scientific studies that have looked at it? Perhaps we have not studied it.

Dr. McAfee, you have got a great program. The cost-benefit numbers look good. It argues for putting people in it. When you look just at the youth cessation end of it—

Dr. MCAFEE. Our decision around it strategically was, as Dr. Fiore and Dr. Hurt had mentioned, is that we go where the evidence leads us, and unfortunately, we have great evidence around adult cessation and we do not have evidence for effectiveness in youth cessation. So we really chose to go for adult cessation, to do a great job of that, and then to go for youth primary prevention in other arenas besides the clinical one because we are still working in that arena and we definitely think this is an area that cries out for further research.

To me, the flip side of this is it is an important message for parents and policy makers that we do not have much to offer their child if they get addicted to nicotine, so it makes it all the more important to avoid that in the first place.

Senator FRIST. Dr. Fiore, your book is great and your summary of it is great. The six points are something we all need to focus on and help educate people broadly. But specifically, you have not looked at the adolescent population, is that correct?

Dr. FIORE. Well, in fact, we did as part of the review process and I will just echo what my colleagues here have said. We have precious little published research, precious little information on how we can effectively prevent adolescents, or help adolescents already addicted to successfully quit.

What the guideline discusses, and there is, in fact, a chapter here on adolescents, is that in the absence of specific information, use what we do know helps with adults. In some instances, specifically, we know that some aspects of that may be helpful. But I think Tim's comment was a real important one. We know how to help adults successfully quit. Let us focus energy, let us focus resources on that, and on the flip side of it, let us focus energy and resources to prevent another generation from ever becoming addicted, because we currently do not have effective treatments for them.

Senator FRIST. Bupropion looks pretty good in adults?

Dr. HURT. It works in adults, and Scott actually mentioned he is doing a study with NIH in adolescents. I would like to just make kind of three points about this whole issue.

The NCI right now is entertaining proposals for research on adolescent smoking cessation, to help adolescents stop smoking. There have been several that have been approved. There is going to be more initiative earlier next year, and that is very, very encouraging.

We get hung up sometimes with low success rates and we get hammered all the time about, well, it only works about 20 percent of the time or 30 percent of the time. Can you not do better? We are dealing with a situation where we have minimum intervention producing those kinds of rates, and I would submit to you that with lung cancer, where the long-term success rate remains at 14 percent, it has been stuck there for a long time, and I do not know how much money is spent every year on the treatment of lung cancer.

Give me those kind of resources and I will figure out how to help your kids to stop smoking, because the success rates we have with adults are very good. The more intense the intervention, the better. Give me a few thousands of dollars, like we do for lung cancer patients, to devote to these kids, as well as the adults, and we can do lots better.

That is just where we are right now. No one thinks anything about it at all, putting more money into lung cancer treatment, which does not work very well at all and has not worked despite all of this.

Senator FRIST. Let me ask you another question, as we are talking about addiction. So far, we have not talked about levels of nicotine. Should we decrease the level of nicotine in a cigarette? Let me just get your thoughts.

Dr. HURT. I think the Heningfield and Benowitz proposal to reduce the level of absolute levels of nicotine in the cigarettes over time would reach a point where there will be a threshold where children, when they started to use, would not get the buzz that Josh talked about. And in the absence of that, then I think that they are right, that they would not become addicted. They are

going to something else later on and would not become addicted to cigarettes.

Senator FRIST. Do all of you agree with that, about levels of nicotine in cigarettes?

Dr. McAFEE. The only caveat is that I think it needs to be thought through and looked at very carefully, because if we just decrease it somewhat, we will end up with another fiasco like we had with low-tar cigarettes, where smokers over-smoke and are smoking more and thereby getting more tar and perhaps getting more cancer. So it has to be thought through carefully and probably would require drastic decreases.

Senator FRIST. This whole fear of lowering nicotine, smoking more, inhaling more—

Dr. HURT. I think that people smoke cigarettes because of the nicotine. There was a cigarette back a few years ago produced by Philip Morris called "Next". It was a de-nicotinized cigarette. Go try to buy some. People do not smoke cigarettes for the smoke and all the other. They smoke for the effects of nicotine.

Senator FRIST. If I were a smoker and I smoked cigarettes with a given nicotine level, if you cut the nicotine level in half, will I be smoking more cigarettes 6 months from now?

Mr. LEISCHOW. Well, either smoking more cigarettes or smoking your cigarette in a different way, because even within a particular cigarette, people can very readily titrate their doses in order to get the nicotine that they want. So maybe a cut in half, it is unclear the degree to which that would really make a tremendous difference.

Dr. HURT. We have to make sure we understand what we are talking about. The current low-tar, low-nicotine cigarettes are not that at all.

Mr. LEISCHOW. Exactly. Right.

Dr. HURT. The tobacco in those cigarettes is the same, whether it is a low-tar, low-nicotine product versus a regular cigarette. The technology is in the ventilation system, where they entrain air into the air that goes into the person and that fools the Federal Trade Commission cigarette smoking machines. They indicate that there are lower levels than there really are.

Senator FRIST. My colleagues ask me this all the time: If I cut the nicotine level in my cigarettes in half, am I going to go out and smoke more, or smoke in a different way, and thereby increase carcinogens in my lungs and still die of lung cancer? I understand that nicotine is the addictive element, or do we know?

Mr. LEISCHOW. It is likely that you will, at least for a while, but we just simply do not have the research to show at what point you really achieve the health benefit of that reduction. I mean, in time, if there are no other alternatives to obtaining nicotine, certainly one would eventually obtain a decreased level.

Dr. FIORE. I think your point is very well taken. We know that people get to a comfortable level, a comfortable daily dose of nicotine and upon changing that or lowering it, they will usually go back to that level. I would be concerned, as one of the interim aspects of lowering the content of nicotine cigarettes, that we have a very clear program in place to deal with the concern that people are going to smoke more to maintain the same levels of nicotine in

their blood, a real important concern. The goal is laudable. The way we get there over 20 or 30 years is concerning.

Senator FRIST. That is obviously my concern as a policy maker, and as a member of the U.S. Senate. It is easy for the government to say: We are going to cut nicotine levels in half in cigarettes. As a result, we feel great. Everybody feels good. Maybe there would be less addiction overall, but in truth, as I understand it, we would be hurting people broadly. You are warning us of something I need to pass on to my colleagues because it is easy just to say, we are going to cut nicotine levels in cigarettes in half. We might feel good, and in effect, we might be hurting people.

Dr. HURT. But if you are talking about youth start-ups, and that is kind of where the question began, the question is, is there a threshold of nicotine in cigarettes, not the vented, low-tar and what, but I am talking about the absolute levels of nicotine in cigarettes that you could reduce it to that would make it so a kid who experimented would not go on to become addicted, I think there is a threshold. I am not exactly sure where it is. These other issues are very, very important, but if the question has to do with youth start-up, the lower the level, I think the less chances they will become addicted, but I do not know exactly what the level is.

Senator FRIST. We need to go on. Senator DeWine, any further questions?

Senator DEWINE. No.

Senator FRIST. I guess there are two things. If possible, I would like to submit questions to you to help educate me and my colleagues, and you can respond in writing.

I do want to thank each of you for an outstanding panel that helps all of us, my colleagues and myself, understand where we are going. Thank you all very much.

Dr. HURT. Thank you for your interest.

Senator FRIST. I am going to ask our third panel to come forward. While they are coming forward, I ask unanimous consent for including Senator Mike Enzi's statement in the record. He is caught in a snowstorm and is on his way back. Without objection, I will include his written statement in the record.

[The prepared statement of Senator Enzi follows:]

PREPARED STATEMENT OF SENATOR MICHAEL B. ENZI

Thank you, Mr. Chairman. I want to commend you for holding this hearing. The proposed tobacco settlement, as a whole, is quite complex and I am pleased that this subcommittee is taking time to focus on its provisions pertaining to youth access to tobacco products. Our Nation's teens must not be sidestepped by a rush to enact the pending settlement.

In 1992, Federal rules—known as the “Synar regulations”—were enacted. These rules threatened States with the loss of Federal grants for drug abuse programs unless they reduced the frequency of tobacco sales to minors. This is a textbook example of how unfunded Federal mandates on States and localities fail to generate results. As a former State legislator and city mayor, I can speak first hand about the difficulties of meeting budget objectives by way of limited resources. It is ever more difficult for State and local

governments to provide public services when the Federal Government is engaged in threats and innuendos.

In addition to unfunded mandates, the Synar regulations recommended that performance be measured by the local authorities' use of children in local sting operations aimed at tobacco retailers. Not only have these federally unfunded, mandated stings proven to be unsuccessful, they send a warped message to teens by injecting them into the enforcement process. For this reason alone, I voted against additional FDA funding for tobacco enforcement programs.

The proposed tobacco settlement has drawn much attention, primarily due to the \$368.5 billion price tag attached to it. From this amount, the FDA would receive an additional \$300 million each year over the next 25 years. I am deeply concerned that this would put all of our eggs into one basket. Although the proposed settlement would eliminate all vending machines, place tobacco products behind the counter, place restrictions on mail orders and establish a nationwide licensing system administered at the State level for all sellers of tobacco products, the settlement would still rely upon youth-driven sting operations as a primary means of enforcement.

I am not convinced, based on the results of the Synar regulations, that the pending tobacco settlement would lower the number of underage smokers. The New England Journal of Medicine recently published a study performed in six Massachusetts communities. The study found that even in communities with enforcement programs strong enough to have cut the frequency of reported illegal sales, teens surveyed said they had little trouble obtaining tobacco. In fact, 58 percent of the under-age youths who tried to buy tobacco in communities with strong enforcement programs were rarely refused. That's only 5 percent lower than the 63 percent of teens who successfully purchased tobacco products in towns with no enforcement programs against tobacco sales to teens. Overall, the study showed that 70 percent of under-age teens who tried to purchase tobacco products succeeded most of the time.

This study reveals how unfunded, youth-driven sting operations failed to generate results. The pending tobacco settlement would administer this same approach from the Federal level. I support much of the work done by the FDA, but I don't believe it has the resources to police the sale of cigarettes in all 50 States and territories.

We must ensure that we have a comprehensive program in place that goes well beyond youth access. Ultimately, our goal should be to end the use of tobacco products by everyone—regardless of their age. I am concerned that a settlement that places too much emphasis on underage smokers, will somehow lend credence to the supposition that the use of tobacco by those who have reached the legal age of 18 is acceptable. The industry understands the youth market too well. It should, since it has quietly courted young smokers for the sake of more profits during the last few decades. The industry needs to comment on this study and provide us with their own ideas on how best to combat these problems. It is not enough for them to just throw some money into a pot and absolve themselves of the responsibility for our current crisis.

I am wholly committed to improving public health, particularly as it relates to smoking-attributable illnesses. Deterring children

from smoking is clearly a back-breaking task that not only demands attention from various levels of government, but from the industry, parents, and our Nation's youth as well. It is without a doubt that we are all stakeholders in this process. We clearly have numerous avenues available that are focused on reducing underage smoking. I intend to participate in reviewing each of these approaches in an effort to enact the most effective and comprehensive policy.

Thank you, Mr. Chairman.

Senator FRIST. In our final panel today, we will hear from two experts on smoking cessation. Our first witness is Paul Schwab, who is the Deputy Administrator of the Substance Abuse and Mental Health Services Administration in the Department of Health and Human Services. He has held a number of high positions in the Health Resources and Services Administration within the Department of Health and Human Services. He has a background in economics and public administration and he has received numerous awards for excellence. His particular area of expertise is workforce health analysis and continuous quality improvement.

Our next panelist is Dr. Joseph DiFranza from the University of Massachusetts. He has published extensively on tobacco, an area in which he has been working for over 17 years. He has focused on tobacco sales to children, including compliance with legal restrictions, and environmental tobacco smoke, among others.

Thank you both for being with us. Mr. Schwab?

STATEMENTS OF PAUL SCHWAB, DEPUTY ADMINISTRATOR, SUBSTANCE ABUSE AND MENTAL HEALTH SERVICES ADMINISTRATION, ROCKVILLE, MD; AND JOSEPH R. DIFRANZA, M.D., UNIVERSITY OF MASSACHUSETTS MEDICAL CENTER, BOSTON, MA

Mr. SCHWAB. Thank you, Mr. Chairman and members of the subcommittee. Thank you for inviting me to discuss implementing the Synar regulation and preventing minors access to tobacco.

I would request that my written testimony be included in the hearing record.

Senator FRIST. Without objection.

Mr. SCHWAB. Thank you. Perhaps I might then just highlight as we go through some of the testimony.

I am pleased to be here to discuss one of the most vital public health issues affecting our Nation, the need to protect our children from the death and disease caused by tobacco use, and let me begin, if I may, by establishing what we view as the necessary framework for the prevention of youth tobacco use.

We know that reaching the goal of prevention of youth tobacco use requires a comprehensive approach that addresses all causes of teenage tobacco use, that it includes all levels of government and all sectors of society. That is why last month, the President called on Congress to enact sweeping tobacco legislation that has as its goal cutting teen smoking by 50 percent in the next 7 years.

After reviewing and analyzing efforts that have been made to prevent youth tobacco use, we believe strongly that comprehensive legislation must address access, issues of availability, and appeal to be truly successful. The framework is important, because as you

know, each day, 3,000 kids become regular smokers, and of these, about 1,000 will eventually die from their tobacco use.

The role of the Substance Abuse and Mental Health Services Administration in this framework is preventing youth access to commercial sources of tobacco through enforcement of State laws, and we take our role seriously. In the 18 months since the regulation implementing the amendment was made final, we have taken numerous steps to ensure that it is implemented fully and effectively and we will continue to do so.

The regulation addresses youth access by requiring each State to have in place laws prohibiting the sale or distribution of tobacco products to individuals under the age of 18 and to enforce those laws in a manner that can reasonably be expected to reduce the extent to which tobacco products are available to individuals under age 18. As part of this, each State must conduct random, unannounced inspections to ensure compliance, develop a strategy and time frame for achieving a noncompliance rate of less than 20 percent, and submitting a detailed annual report. We are working with States to provide them with the support they need to facilitate the implementation of these requirements and are pleased with the States' progress to date in identifying outlets, establishing sound sampling plans, and working with us collaboratively.

We are currently in the fourth applicable year of implementation for most States. At this point, all States have tobacco laws prohibiting tobacco sales to minors and have submitted their inspection methodologies and sampling designs. All States are on target with regard to negotiating their baselines and target rates, which are incorporated in the substance abuse block grant applications. At this time, States are submitting for our review the results from the second year of statistically valid inspections, and I would be happy to go into that as we talk.

The data show to this point that enforcing State laws have produced positive results. Prior to the release and implementation of the Synar regulation when we have looked at individual studies on sales rates, it would appear that noncompliance rates were in the range of 60 to 100 percent. The current data is quite preliminary, but it does point to a downward trend in the sales of tobacco to minors.

To facilitate implementation and assist in bringing down the rate of noncompliance, our agency, SAMHSA, has taken a number of steps to provide States with technical assistance, in brief, including intense collaboration with individual States and our agency's officials, technical assistance conference, guidance documents, individual tailored technical assistance contacts, video development, and collaboration with other Federal agencies and non-Federal organizations. This technical assistance is an important part of ensuring a reduction in youth access and we are seeing some progress.

In line with what research and experience have told us, the States that have actively enforced their laws over the years have reduced their violation rates substantially. We believe that the first year results suggest that continued compliance with the regulation will lead to a greater decline in violations.

Also, States have substantially advanced their knowledge and understanding of sampling and monitoring requirements as part of

implementing the regulation and we do expect to reach our ultimate goal of achieving an inspection violation rate of less than 20 percent by the year 2002.

We still have a long way to go in fully addressing youth tobacco use. Continued efforts need to be made to understand why youth use tobacco and what action needs to be taken to eliminate those motivators. The reasons that youth begin to use tobacco are very complicated and involve not just access to the product but also the appeal for the product.

Our regulations that we are implementing place the responsibility for preventing youth access on the States, but we know that it will take much more than eliminating access to commercial sources of tobacco to prevent youth tobacco use. That is why a comprehensive approach is required and comprehensive legislation should be enacted.

In conclusion, our experience in prevention has taught us that there is no single best approach to preventing youth tobacco use. We know that to reduce use, it will take a concerted effort and collaboration at all levels of government and in all sectors of society. SAMHSA will continue to provide leadership on this important issue in its implementation of the Synar regulation and we will work closely with our public health partners to coordinate our efforts. We welcome the opportunity to be part of this important prevention effort. We thank you and I thank you for your time and for your support.

Senator FRIST. Thank you.

[The prepared statement of Mr. Schwab follows:]

PREPARED STATEMENT OF PAUL SCHWAB

Mr. Chairman and Members of the Subcommittee: Thank you for inviting me to discuss implementing the Synar regulation and preventing minors' access to tobacco. My name is Paul Schwab. I'm the Deputy Administrator for the Substance Abuse and Mental Health Services Administration.

I am pleased to be here to discuss one of the most vital public health issues affecting our Nation: the need to protect our children from the death and disease caused by tobacco use. Let me begin by establishing what we view as the necessary framework for the prevention of youth tobacco use. We know that reaching the goal of prevention of youth tobacco use requires a comprehensive approach that addresses all causes of teenage tobacco use and that includes all levels of Government and all sectors of society. That is why, on September 17, the President called on Congress to enact sweeping tobacco legislation that has as its goal cutting teen smoking by 50 percent in seven years.

After reviewing and analyzing efforts that have been made to prevent youth tobacco use, the Administration believes strongly that comprehensive legislation must address access, availability, and appeal to be truly successful. A comprehensive framework is important because, each day, 3,000 kids become regular smokers, and, of these, about 1,000 will eventually die from their tobacco use. The net effect of this is that among children living in America today, 5 million will die an early preventable death because of a decision made as a child. We must not assume that there is one single action that will prevent these deaths. We all have a role to play in addressing access, availability, and appeal.

The role of SAMHSA in this framework particularly as reinforced by Congress in the Synar Amendment, is preventing youth access to commercial sources of tobacco through enforcement of state laws, and we take our role seriously. In the eighteen months since the regulation implementing the Synar Amendment was made final, we have taken numerous steps to ensure that it is implemented fully and effectively and we will continue to do so. We understand the impact that such a regulation could have on youth access to tobacco. But we also believe that, to reach the president's goal, we need more than these regulations. We need comprehensive legislation that includes the five principles that the President announced last month.

What the Regulation Requires

The Synar regulation addresses youth access by requiring each state to have in place laws prohibiting the sale or distribution of tobacco products to individuals under the age of 18 AND to enforce those laws in a manner that can reasonably be expected to reduce the extent to which tobacco products are available to individuals under age 18. Each state must:

- 1) conduct random unannounced inspections to ensure compliance,
- 2) develop a strategy and time frame for achieving a non compliance rate of less than 20 percent, and
- 3) submit an annual report detailing the state's activities to enforce the law, the state's overall success, the way in which inspections were conducted, the methods for identifying outlets, and the state's plans for future activities.

We are working with the states to provide them with the support they need to facilitate the implementation of these requirements. We are pleased with the states' progress in identifying outlets and establishing sound sampling plans, and we have observed effective collaboration within individual states on policy issues and identifying resources for support of compliance requirements.

State of Implementation

We are currently in the fourth applicable year of implementation for most states. At this point, all states have tobacco laws prohibiting tobacco sales to minors and have submitted their inspection methodologies and sampling designs. All states have negotiated their baselines and target rates which were incorporated into their FY 97 block grant applications. All states have received their grant awards. At this time, states are submitting, for SAMHSA's review, the results from their second year of statistically valid inspections.

The data shows that enforcing state laws have produced positive results. Prior to the release end implementation of the Synar regulation, studies on sales rates own records non—compliance rates in the 60 to 100 percent range, with considerable variability depending on the tobacco source. The current data is quite preliminary but points to a downward trend in the sales of tobacco to minors.

Official baseline sales rates were negotiated between SAMHSA and each state with regard to the nature of the random sample survey methodology employed by the state. Baseline noncompliance rates range from below 10percent to over 70 percent. States will, lower rates were found to have engaged in significant enforcement activities over a period of several years, prior to implementation of Synar.

SAMHSA's Role

To facilitate implementation and assist in bringing down the rate of non-compliance, SAMHSA has taken a number of steps to provide states with technical assistance, including:

- 1) Intensive collaboration between individual states and SAMHSA officials,
- 2) Two technical assistance conferences (2/96 and 11/96) to provide states with guidance and assistance with compliance requirements,
- 3) Three guidance documents on sampling design inspection methodology, and implementation strategies,
- 4) Individual contact with those states having difficulty meeting the compliance requirements,
- 5) Development of a video to assist states in training minors to conduct inspections, and
- 6) Collaboration with other agencies such as FDA, CDC, and NIH at the Federal level, as well as organizations at the Federal, state, and local level to support enforcement activities.

This technical assistance is an important part of ensuring a reduction in youth access, and we are seeing some progress. In line with what research and experience have told us, the states that have actively enforced their laws over the years have reduced their violations rates substantially. We believe that the first-year results suggest that continued compliance with the Synar regulation will lead to a greater decline in violations. In addition, states have instituted new and successful collaborations among law enforcement agencies, health groups, Departments of Health and Substance Abuse, Department of Agriculture, community activists, and retailers.

States also have substantially advanced their knowledge and understanding of sampling and monitoring requirements. We expect to reach our ultimate goal of achieving an inspection violation rate of less than 20 percent by the year 2002, and we anticipate that this achievement, together with interventions targeting appeal and availability, will facilitate a reduction in the number of youth who use tobacco.

The Future

We still have a long way to go, however, in fully addressing youth tobacco use. Continued efforts need to be made to understand why youth use tobacco and what action needs to be taken to eliminate those motivators. The reasons youth begin to

use tobacco are very complicated and involve not just access to the product through self-service displays and vending machines, for example, but also the appeal that advertisements and sponsorship create for the product. The Food and Drug Administration's final rule addresses these access and advertising issues very effectively. Further, we know that the price of tobacco has an impact since studies show that a 10-percent increase in cigarette prices leads to a 7-percent reduction in teen smoking. That is why the President has called for Congressional action to increase the price of cigarettes by as much as \$1.50 per pack using a combination of penalties and payments.

The Synar regulation places the responsibility for preventing youth access on the states, but we know that it will take much more than eliminating access to commercial sources of tobacco to prevent youth tobacco use. That's why a comprehensive approach is required and comprehensive tobacco legislation should be enacted.

Conclusion

Our experience in prevention has taught us that there is no single best approach to preventing youth tobacco use. We know that to reduce youth tobacco use, it will take concerted effort and collaboration at all levels of government and in all sectors of society. SAMHSA will continue to provide leadership on this important issue and will work closely with our public health partners to coordinate our efforts. We welcome the opportunity to be a part of this important prevention effort.

Thank you for your time and your support. I will be pleased to answer your questions.

Senator FRIST. Dr. DiFranza, welcome.

STATEMENT OF JOSEPH R. DIFRANZA, M.D.

Dr. DIFRANZA. Thank you for the opportunity to address the committee today. I represent Stop Teenage Addiction to Tobacco, which stands for STAT, and for the past 11 years, STAT has campaigned for restrictions on the sale of tobacco to youth. Our members have conducted much of the scientific research concerning the sale of tobacco to minors and I would like to share some of our knowledge with you today.

Underage smokers consume well over \$1 billion worth of tobacco each year, and young smokers like Josh tell us that the vast majority of their tobacco is purchased directly from tobacco retailers. If \$1 billion in illegal sales were spread out evenly over an estimated one million tobacco retailers nationwide, it would indicate that the average tobacco retailer makes about \$1,000 in illegal sales each year, or breaks the law about 500 times each year.

The foremost question regarding the sale of tobacco to youths should be, if we could prevent the illegal sale of tobacco to children, would it reduce the number of youths who use tobacco? There are now three published reports and two other unpublished reports that I am aware of, of communities which have seen substantial reductions in youth smoking rates after merchants were forced to curtail their illegal sales of tobacco.

In Woodridge, IL, there was a 69 percent decline in teenage tobacco use. This 69 percent decline persisted as these children were followed for 5 years, until the point where they had all graduated from high school. So even when these youths were 19 years old, they still had a marked decline in smoking compared to surrounding communities.

In Leominster, MA, where I was doing the enforcement myself, I found a 42 percent decline in smoking among the teenagers there. In a community in Washington and in other communities in other States—like I said, these studies have not been published yet, so I cannot give the details, but they have also seen declines in smok-

ing among the teenagers when they did a good job of enforcing the law.

So the answer is, yes, if enough merchants are forced to obey the law, it can have an effect on the number of teenagers who smoke.

The next logical question is, well, how many merchants have to obey the law before you really see an impact? We measure this merchant compliance by sending underage decoys into each store to see if they can buy tobacco. In the communities that we have seen reductions in youth tobacco use, they have been reporting 95 percent of the merchants were obeying the law on any given day.

In two recent studies, it was found that when only 80 percent of the merchants were obeying the law, it had no effect on tobacco use, and unfortunately, one of these studies was mine. It was published about 2 weeks ago in the New England Journal, and we were certainly hoping to see a tremendous impact on youth smoking. But what we found was that 80 percent of the merchants were obeying the law. The other 20 percent were not, and the kids had no trouble identifying that 20 percent of the merchants to go and buy their tobacco from them.

Hence, enforcement of these laws has little, if any, effect unless the enforcement is vigorous enough to convince all the stores in a community to make it a policy not to break the law. When all the stores have made it a policy not to break the law, you will measure compliance at about 95 percent, and that is because of the random human error that is unavoidable. But what we want to achieve is the point where all of the stores at least have the policy that they will not sell, even if the clerk will make an occasional mistake. That way, the teenagers never know which store to go to on any given day because all the stores have the same policy.

What does it take to achieve 95 percent compliance? Well, the answer is vigorous enforcement with frequent compliance tests of all merchants. In Woodridge and Leominster, the two communities I have cited, every merchant is tested four times each year. It may be possible to enforce the law with less frequent tests if the penalties are more substantial. It should be remembered that the average retailer takes in about \$1,000 in illegal sales each year. Dishonest merchants may take in several times this amount. The penalties have to be stiff enough to outweigh the benefits of breaking the law.

I see the National Convenience Store Association is sponsoring H.R. 2034, making it the maximum penalty for anybody selling tobacco to minors would be \$25 for a first offense, so it is going to be hard to stop a \$1 billion crime ring with a maximum fine of \$25.

Senator FRIST. That fine is on the clerk or on the store?

Dr. DIFRANZA. On the clerk, and the stores are completely let off the hook.

What would be the cost of inspecting one million merchants four times each year? Well, some private organizations are now contracting with different States to conduct inspections at \$17 apiece, and if you added in 20 percent overhead for the State agency who is supervising the enforcement, four million inspections each year would cost \$82 million a year. If the government were to do these inspections at a typical cost of \$100 per inspection, which is what

the going rate is in many States now, with a 20 percent overhead, it would \$440 million per year.

In either case, it would cost a lot less than the \$1 billion that is being taken in each year from these illegal sales. I might mention that the Federal Government takes in in the neighborhood of \$150 million each year from these illegal sales to children.

The Department of Health and Human Services is under a statutory requirement to withhold block grant funding from States that do not enforce their laws in a manner, as we just heard, which can be reasonably expected to reduce the availability of tobacco to minors. The current regulations require States to only reach an 80 percent rate of compliance, and we see that it is going to be another 5 years before States are required to reach that rate.

Based on a current scientific data, such a low rate of compliance cannot be expected to reduce youth access to tobacco. Hence, the current regulations do not meet the statutory requirements of the Synar law and the current Federal effort to deal with the problem of illegal sales will be a failure unless the regulations are updated to reflect our current knowledge by requiring higher compliance rates.

Finally, while the global settlement would provide funding for enforcement of State youth access laws, it provides no assurances and no guarantees that the law will ever be enforced in a manner which will achieve the level of compliance needed to actually impact teen smoking. Indeed, the settlement actually allows States 10 years to achieve a compliance rate of 90 percent. If States actually took this long, the enforcement provided by the settlement would have no impact on youth access to tobacco for at least 10 years.

I will end my opening statement there and invite any questions you might have.

Senator FRIST. Thank you, Dr. DiFranza.

[The prepared statement of Dr. DiFranza follows:]

PREPARED STATEMENT OF JOSEPH R. DIFRANZA, M.D.

Thank you for the opportunity to address your committee today. I represent Stop Teenage Addiction to Tobacco. For the past eleven years STAT has campaigned for restrictions on the sale of tobacco to youths. Our members have conducted such of the scientific research concerning the sale of tobacco to minors and I would like to share some of our knowledge with you today.

Underage smokers consume well over \$1 billion worth of tobacco each year. Young smokers tell us that the vast majority of their tobacco is purchased directly from tobacco retailers. If \$1 billion in illegal sales were spread out evenly over an estimated 1 million tobacco retailers nationwide, it would indicate that the average tobacco retailer breaks the law about 500 times each year.

The foremost question regarding the sale of tobacco to youths should be "If we could prevent the illegal sale of tobacco to children would it reduce the number of youths who use tobacco?" There are now three published reports of communities which have seen substantial reductions in youth smoking rates after merchants were forced to curtail their illegal sales of tobacco. In Woodridge, IL there was a 69 percent decline in teen tobacco use. In Leominster, Massachusetts I found a 42 percent decline. So the answer is, "Yes, if enough merchants are forced to obey the law, it can have a strong impact on teenage smoking rates."

The next logical question is "how much is enough?". We measure merchant compliance with the law by sending underage decoys into stores to see if they can buy tobacco. In the communities that have seen reductions in youth tobacco use, about 95 percent of merchants were obeying the law on any given day. In two recent studies it was found that when only 80 percent of merchants were obeying the law, it had no effect on tobacco use. Youths learned which stores were happy to break the law and frequented those stores over and over. Hence enforcement of these laws has

little if any effect unless it is vigorous enough to convince all stores in a community to make it a policy not to break the law. When all stores make it a policy not to sell tobacco to minors, compliance will be about 95 percent due to an occasional random human error.

"What does it take to achieve 95 percent compliance?" The answer is, vigorous enforcement with frequent compliance tests of all merchants. In Woodridge and Leominster every merchant is tested four times each year. It may be possible to enforce the law with less frequent tests if the penalties are substantial enough. It should be remembered that the average tobacco retailer takes in about \$1,000 in illegal sales each year. Dishonest merchants may take in several times this amount. The penalties have to be stiff enough to outweigh the benefits of breaking the law.

"What would it cost to inspect one million merchants four times each year?" If the inspections were contracted out to private agencies at a cost of \$17 per inspection with 20 percent overhead for the enforcing agency, four million inspections would cost \$82 million per year. If done at a typical government agency cost of \$100 per inspection with 20 percent overhead, it would cost \$440 million per year. In either case, it would cost a lot less than the \$1 billion that is being taken in from these illegal sales each year.

The Department of Health and Human Services is under a statutory requirement to withhold block grant funding from States that do not enforce their laws in a manner which can be reasonably expected to reduce the availability of tobacco to minors. DHHS regulations require states to reach only an 80 percent rate of compliance. Based on current scientific data, such a low rate of compliance cannot be expected to reduce youth access to tobacco. Hence DHHS is failing to meet the statutory requirements of the Synar law and the current Federal effort to deal with the problem of illegal sales will be a failure unless the regulations are updated to reflect our current knowledge.

while the global settlement would provide funding for enforcement of State youth access laws, it provides no assurances and no guarantees that the law will ever be enforced in a manner which will achieve the level of compliance needed to actually impact teen smoking. Indeed, the settlement actually allows states ten years to achieve a compliance rate of 90 percent. If States actually took this long, the enforcement provided by the settlement would have no impact on youths' access to tobacco for 10 years!

I will end my opening statement there and invite any questions you might have on this topic.

Senator FRIST. I guess, Mr. Schwab, we ought to key right in on this last point. Dr. DiFranza's testimony suggests that a system of enforcement that is less than 95 percent effective will not meet the objectives of lowering teen smoking. This is based on his most recent study and other work. The agency has said 80 percent. Progress, as you said, is being made in increasing compliance in this area over time. How do you respond to this whole concept of a 95 percent threshold?

Mr. SCHWAB. Well, in our analysis, Senator, we are, indeed, early in the implementation of this program. In fact, as we have indicated, this is the first year, this past year, where we are even getting now baseline rates for 40, 43 States. So we really do not have a track record yet from the standpoint of the program as far as assessing it.

In designing a national program, our assessment has been based on individual information and analysis to this point that 80 percent is a reasonable, realistic national norm to work from as far as a national effort is concerned.

The study here, as some of the other studies, clearly have focused on individual communities, and as we approach this, trying to establish a reasonable, achievable national rate where there would not be safe havens, in that sense, where it becomes blanketed across the country, that 80 percent is a reasonable target. Also, that the time frame is an achievable and a reasonable one, as well.

We recognize that under any circumstances, other interventions will be necessary to really focus on this as part of any kind of a comprehensive effort, but in that, we do not see that as being unachievable.

Senator FRIST. Dr. DiFranza, you made very clear that the use of inspections four times a year is one measure of compliance, maybe the only measure you can study easily, but that there are other penalties that could possibly achieve the same enforcement. Has anybody looked at the flip side of that: instead of just punishing, how would we reward the convenience store operator, the place where the cigarettes are sold, for doing a good job, for not selling to under-age youth, which is a \$1 billion problem? Has anybody studied it?

Dr. DIFRANZA. That was the first thing we studied, actually. Before we actually started to do the enforcement, we decided to use the carrot approach and when we first did our compliance checks, we only publicized the names of the stores that were doing a good job because we were trying to generate good publicity for the stores. There were no fines for the stores that did a poor job, in other words, that were making these illegal sales.

Unfortunately, we found we could only get the compliance rate up to about 50 percent, 70 percent with the carrot, and what we were seeing was that the good stores are losing their adolescent smoking business to the bad stores, and at that point we started to do the enforcement.

The tobacco industry itself has a program called "It's the Law" that they have had around since 1990 to educate merchants about the sale of tobacco to minors and they have stickers and videos and pins that the clerks would wear. I actually did a study to see if this was effective, because we were using a similar approach of merchant education. We went to 480 stores. Half of them were participating in this "It's the Law" program and the other half were not and we found no difference in the behavior. In other words, those stores that had been fully trained by the tobacco industry, had the signs up that say, "We do not sell to minors," were just as likely to break the law as the stores who were not educated. So, unfortunately, education did not work.

Senator FRIST. Senator DeWine.

Senator DEWINE. Thank you. Mr. Schwab, you were talking about the 80 percent compliance and you described this as reasonable, that this was a reasonable goal. My question would be, is it effective? I mean, you have heard Dr. DiFranza's testimony where he, in essence, is saying, if you do not hit 90 or 95 percent, you are really not getting the job done. Do you want to address that for me?

Mr. SCHWAB. We believe that it is effective if done on a national basis. If we are looking at a rate that is reached in every State of the country as a national rate, we believe that that will have a positive effect. But I think it is important to acknowledge and to comment that we would not look at this particular program as a necessary and sufficient condition of what we are talking about here. We will continue to need other parallel approaches and not just rely on this specific program in affecting the use of tobacco by youth. So we are looking at it effectively as a national program,

that, in fact, it will indeed have a positive effect in bringing down teen smoking.

Senator DEWINE. I do not know which one of you is right. Obviously, you two disagree on this, but I want to explore this with you a moment.

Mr. SCHWAB. OK.

Senator DEWINE. It would seem to me, and just bear with me for a moment, it would seem to me that as a teenager who is going to go buy cigarettes, what happens nationally really is not too relevant. What is relevant is what is in my market.

Now, what the doctor says is that you have to get 90 or 95 percent within that market to really have an effect, because if I can still buy it and buy it relatively conveniently, it does not mean that if there are 20 places that I cannot buy it but if there are two that I can, well, I can still buy it. That is what he is saying. I do not know if he is right or not, but that is what he is saying. I do not think you are addressing that. I do not hear you addressing that in response to my question.

Mr. SCHWAB. The issue becomes whether, as part of access, there are available opportunities for youth to have alternative sources for tobacco and also, for example, alternative commercial sources. If you have 95 percent in community "x" but across the street in community "y" these young people are able to have access, it raises some question in terms of the effectiveness.

Senator DEWINE. Oh, sure. It depends on how you define a community and, basically, what is readily accessible to me. But basically, you two disagree. You say 80 percent does the job. You say you have to get 95 percent.

Mr. SCHWAB. Well, we are talking about, at least in part, a difference between what becomes an anticipated effective rate across the country versus what might be an effective rate in an individual community, and they may not necessarily be the same, depending in terms of what is happening in surrounding communities and what happens in terms of other aspects as far as access to tobacco.

Our assessment is that across the Nation in terms of developing a national norm, that as part of an integral part of dealing with access issues, 80 percent can very well be effective.

Senator DEWINE. I do not understand that answer, but I am going to go on. Who came up with the 80 percent? That is your Department's, right?

Dr. DIFRANZA. Are you asking me?

Senator DEWINE. Either one.

Dr. DIFRANZA. I will give you the research and then you can—

Senator DEWINE. I want to know who came up with the 80 percent, though.

Mr. SCHWAB. As far as the Department is concerned—

Senator DEWINE. I mean, that is the goal, right?

Mr. SCHWAB. We had identified 80 percent and that really was developed as part of some of the assessment of available information and discussion with experts around the time of the mid-1990s, looking at our Healthy Year 2000 objectives.

Senator DEWINE. Dr. DiFranza.

Dr. DIFRANZA. The 80 percent I was quoting was the result of a study we did in Massachusetts, where we had six communities and

we surveyed 20,000 youths to see where they were getting their tobacco. The communities in which these youths were living achieved an 80 percent compliance rate and we asked them, how often are you turned down when you try to buy tobacco? How easy is it to buy tobacco? Before and after, the kids did not really notice that we were doing the enforcement because they were not having any more difficulty buying tobacco.

Now, in another community, the Leominster example, we had 94 percent compliance. I went in and interviewed a couple dozen of the children living in those communities and asked them, can you buy tobacco, and they would say, no, you cannot buy tobacco in Leominster, period. I asked about 20 smokers and only one out of the 20 said he was able to buy tobacco. The other 19 said, no, I cannot go into any store in town and buy tobacco.

So that is where we get the 94 percent or in the 90s and the 80 percent comes from my other study. Now, there is another study that was just done in a dozen communities in New York in which they also achieved an 80 percent compliance and they had identical results. The kids had no trouble going into stores to buy tobacco because they knew which ones were selling to them.

Of course, we do not have any national data on what 80 percent compliance would do to youth access across the Nation, but I agree with you that kids only shop in their neighborhood and so what really is going to impact the kids is what the compliance rate is in their individual community.

Senator DEWINE. Mr. Schwab, do you have the figures per State for compliance today? Are they available to us?

Mr. SCHWAB. We will be able to provide them to you.

Senator DEWINE. How soon is that available?

Mr. SCHWAB. What we are now trying to do is putting together a complete report, and I would say within the next few weeks, we will have that available to you.

Senator DEWINE. So we will be able to look at that and see what each State in the Union plus the District of Columbia has as far as compliance rate?

Mr. SCHWAB. Well, the way the program is administered, that will be able to provide you with the baseline rates for 43 States. There are seven States where the baseline rates are in the process of being set up this year because they had every-other-year legislatures meeting. So for this past 1997, we will have the rates for 43 States.

Senator DEWINE. Just so I am sure and I understand fully what I am going to get and what I am going to see, when I see for the State of Ohio or the State of Idaho or Tennessee a figure, and you call that a compliance rate figure, describe in layman's terms what that percentage will mean. What does that mean when I see that? What does that represent?

Mr. SCHWAB. This will be a noncompliance rate and it will show what percentage of retail outlets were in violation of the State law in terms of access of youth under the age of 18.

Senator DEWINE. And the sampling technique, though, would be what?

Mr. SCHWAB. We have—

Senator DEWINE. So you are not in compliance. What does that mean? I was not in compliance 1 day of the year? How do you figure that? Just tell me how you do it. I just do not know how you do that.

Mr. SCHWAB. We have worked with the States, working from developing lists of retail outlets in the State and a sampling methodology to go in and inspect and on the basis of that inspection coming up with a percentage of either being in compliance or not being in compliance, and these rates will be based on those inspections in the course of the year, what is noncompliant.

Senator DEWINE. I am trying to get this in simple terms. Would that mean that, let us say a State had a 30 percent noncompliance rate. Would that mean that I would expect that if I sent an underage person into 100 stores in that State, in 30 of them, they could buy? Is it that simple? Is that what it means?

Dr. DIFRANZA. That is it.

Mr. SCHWAB. Yes. On a sampling basis, yes.

Senator DEWINE. On a sampling basis.

Mr. SCHWAB. Thirty percent, three out of ten would be in non-compliance with the State law.

Senator DEWINE. One hit. I mean, basically, I send one person into 100 stores, they are underage, they go in, and 30 times, they buy. Seventy times, they do not buy. That is 30 percent noncompliance. That is what that means?

Mr. SCHWAB. We are talking about, yes, 30 outlets out of 100. But again, this is done on the basis of working through a list of outlets, working through a sampling design, working through inspection protocols, but yes, that is the rate that would be the result. I mean, that is what we are talking about.

Senator DEWINE. Yes. I do not care about your sampling technique. I trust that you can do that.

Mr. SCHWAB. That is what we are talking about, and when we talked about 80 percent or in a particular study that has been developed—

Senator DEWINE. The two of you agree on the methodology?

Dr. DIFRANZA. Yes, sir. I did the study for Massachusetts.

Senator DEWINE. It is just a question of one of you thinks it does not have much effect until you get to 95 percent and you think it does at 80 percent.

Mr. SCHWAB. Again, and I do not want to get too detailed in terms of critique of studies. I think that a number of studies in some of the individual communities have focused on control groups and intervention groups where it is easy for someone to cross the street and one has to raise some questions about the validity of the numbers.

Senator DEWINE. Obviously, I am asking the question, so I think it is relevant. But it is relevant, I think, because Congress has to look, is the Synar law working correctly? We have to look quite bluntly to see whether you are interpreting it correctly and whether your regulations comply the way we think it should with the Synar law.

Then the bigger picture is, we have to look, as we discussed with our two previous panels, as we look at the whole issue of reducing underage smoking in this country and we look at the three or four

or five different components that comprise our efforts to get that done, what we are talking about in this panel with the two of you is one of the components, which is the enforcement component, and we have to know if that has to be adjusted, I think, and we have to have some expectation of where we are going to be in 2 years and 4 years and 6 years and 10 years.

Mr. SCHWAB. I think as a matter of perspective, Senator, if I may, I do not believe that Dr. DiFranza and I are in disagreement, that whether the true number ultimately is 80 percent or 95 percent, that focusing in on compliance and stores and this issue alone is not going to be sufficient to significantly affect the issues that we are talking about here, that under any circumstances, we will need a comprehensive approach.

Senator DeWINE. And I think we all get that and I think we all understand it and I think that is a point very, very well taken.

I have gone way over my time. I have just one last comment, though. I think it is significant in Congress and in government that we not do things that we think are having an effect when they really are not. So if 80 percent is the goal that we are all fighting for and if the truth is that 80 percent does not get us a whole lot, then we ought to reassess what we are doing. We ought to stop moving toward the 80 percent or maybe we ought to raise the bar up a little bit.

I do not know what the correct answer is, but Dr. DiFranza's testimony, to me, just as a layperson listening to this, seems to make a lot of sense, because I know teenagers and I know they can get the job done. If they want to go do something, they can figure out a way to do it unless there are an awful lot of obstacles put in their path. Thank you.

Mr. SCHWAB. If I may, just one last point to that.

Senator FRIST. Sure.

Mr. SCHWAB. I think from our perspective, it indeed would be preliminary to say that we clearly need a higher number than 80 percent, but I would say, Senator, that we will be involved, as we are now, on an ongoing basis evaluating the program. It is early to assess that, and I might add that my colleague, in that sense, I guess Dr. DiFranza as part of an RWJ program, will also be independently assessing the Synar regulation and its implementation so that there will be two opportunities to take a look at the issue of effectiveness of the bar.

Senator FRIST. Dr. DiFranza, you have noted in previous testimony to the Senate that the average retail clerk is around about 88 days on the job.

Dr. DiFRANZA. That is right.

Senator FRIST. Are there any creative approaches to training these clerks that would in some way make them take this responsibility, this law of the land, more seriously?

Dr. DiFRANZA. I think the training programs that are available for clerks are excellent. The tobacco industry actually has done a good job in this area. They have glossy materials. They have videotapes. They have calendars you can peel off to say you have to be born before this day in 1979 in order to be able to buy tobacco. The materials available for training the clerks is excellent. What may

be lacking is the management taking the time to train the clerks and to take the job seriously.

Senator FRIST. Do we know that for a fact? Are there data out there studies that have been done? That is the logical conclusion, other than the clerk does not care. But is it a fact, do you think, that the management is not instructing clerks not to sell cigarettes?

Dr. DIFRANZA. Yes. I believe that is the case. Initially, when we—well, this has transformed over the years. Initially, at my first survey, we asked the clerks, is it against the law to sell tobacco to kids, and about 75 percent of the clerks did not even know that there was a law against selling tobacco to kids.

Now when we go in, we hear, the kids always hear that, well, they are enforcing the law. I have to be careful. You might be working for the Board of Health. We have to check I.D.s. So now I am convinced that about 100 percent of all the clerks who are selling tobacco know there is a law and that they are supposed to be obeying it. How seriously they take it is another matter. So I think the clerks have been educated. They know now that there is a law. They know they are supposed to be checking I.D.s.

Senator FRIST. So you would conclude that the clerk sells these cigarettes illegally, knowing it is illegal, because their management has not stressed to them that they should not do that?

Dr. DIFRANZA. I think part of it is there is no—I do not agree with the tobacco industry's approach of putting all of the responsibility on the clerk and then the multi million dollar national organization that runs the store is completely free and clear of any responsibility for these illegal sales. So I do think that it is a reasonable approach to put some of the penalty on the clerk and some on the management.

Senator FRIST. Put it in perspective for me. A billion dollars in illegal sales every year to minors. Of that \$1 billion, how does it break down, on a percentage basis: convenience stores, grocery stores, supermarkets, whatever? I do not know how you chart that sort of thing, but just give me some perspective. Where do people buy these cigarettes illegally?

Dr. DIFRANZA. About 30 percent of tobacco sales are from convenience stores. This is just off the top of my head. Vending machines are the easiest place for children to buy tobacco, but they are much more expensive there, so that is a last resort and maybe only five percent of kids are using vending machines. Grocery stores, it is easy to buy there but you have to wait in line. Probably gas stations are the easiest place for kids to buy. Often, their friends work there, pumping gas, and will be happy to sell them cigarettes.

Senator FRIST. Could you try to get that data and submit it to the committee? I am sure it is available somewhere. I just have not read it. As a focus of this hearing, I am less interested in overall sales of cigarettes than in this \$1 billion illegal adolescent market, with regard to where that is taking place.

Dr. DIFRANZA. I would be happy to provide that.

[The information of Dr. DiFranza follows:]

UNIVERSITY OF MASSACHUSETTS MEDICAL CENTER
Boston, MA, November 3, 1997.

The Honorable Bill Frist,
United States Senate,
Washington, DC.

DEAR SENATOR FRIST: Thank you for inviting me to testify before your subcommittee on Youth and Tobacco. In response to your request I am enclosing several articles regarding merchant education and would like to add the following comments to the record of my testimony.

I was one of the pioneers of merchant education when I began work in this field over ten years ago. It was my initial hope that if merchants were educated about the illegal sale of tobacco to minors they would obey the law. Unfortunately, a wide variety of educational programs instituted in a variety of settings have proven inadequate to stem this illegal activity.

The modest improvements in merchant behavior that sometimes occur after educational programs appear to result from convincing merchant's that they will be caught and penalized. When enforcement does not follow, the perceived threat disappears and merchants return to their old behaviors.

There have already been extensive trials merchant education conducted by academics and industry. I have designed and delivered many of these programs myself. I have personally worked with individual tobacco retailers, convenience store chains, local enforcement authorities and even the convenience store association in delivering merchant education programs. The manufacturers and the convenience store associations have each widely distributed merchant education materials, investing millions of dollars. I have very little criticism of the materials the industry has used in these programs. The issue of illegal sales to minors has also been reported on repeatedly in tobacco industry trade journals. Despite the fact that every tobacco merchant must now know that it is illegal to sell tobacco to minors, this illegal practice remains widespread. The scientific studies included here demonstrate that merchant education programs are not effective in curtailing this illegal activity.

Despite my early optimism and participation in these educational programs, I must now conclude that attempting to solve this problem through education would be like trying to shut down the Columbian drug cartels by sending a small delegation of health educators to enlighten the drug lords. The sale of tobacco to children represents well over \$1 billion in illegal activity each year. The recipients of this money are not going to be easily persuaded to give it up. At this point, any further pursuit of merchant education as an option would be seen as a cynical tobacco industry ploy to forestall the effective enforcement of youth access laws.

The reason that this illegal activity continues is that authorities all over this nation are too afraid to enforce the law. Officials would rather see generation after generation of youths develop the addiction that Josh described for us than face the political heat that the convenience store association will generate if their members are actually penalized for breaking the law. The problem of illegal tobacco sales to children will continue unchecked as long as government authorities are more afraid of enforcing the law than merchants are of breaking the law.

I see this is a conservative, law and order issue. Rhetoric about coddling criminals could be aptly used to describe the lack of action taken against merchants who violate this law. Over and over the federal government has declared a war on the sale of illegal drugs. I have yet to hear an elected official say that the illegal sale of tobacco to children is illegal, morally indefensible, and something that will not be tolerated. Will I ever hear the government declare war against the illegal sale of tobacco to children? I hope that this is the message that will come out of the settlement discussions.

If I can be of any further help to you or your staff please let me know.

Sincerely,

JOSEPH R. DiFRANZA MD.

[The articles referred to are retained in the files of the subcommittee.]

Senator FRIST. You mentioned that the penalty of \$25 on the clerk was insufficient. Do you think that the noncompliance fines should be shared, then, among store owner, management, and clerk?

Dr. DiFRANZA. I do, yes, and I can give you examples of recent times when we sent out kids into the store. A couple clerks said, "I cannot sell them to you now. My boss is looking." A couple of

store owners, one, I was waiting for my kid to come back out of the store and they never came out and it was, like, five minutes later. What happened was the store owner says, "This is illegal," and he took the kid out into the back alley behind the store and sold him the tobacco outside the store. Another merchant told my daughter, he put the cigarettes in a brown paper bag and told her to keep it in the bag until she got at least a block away from the store because the police are watching.

So these are clearly instances where both the clerks knew they were breaking the law but they did it anyway, where the owners of the store knew that they were breaking the law but they were doing it anyway.

Senator FRIST. You say that a \$25 fine on the clerk is too little and there are some States that have a \$2,500 fine for each sale of cigarettes to minors. The feedback that I get is that a \$2,500 fine is so high that it is hard to get anybody to enforce that? Is there some range that we should be thinking of that works, based on your studies?

Dr. DIFRANZA. There is no research on that. Woodridge uses a \$300 fine for the first offense and \$500 for the second. Leominster was using a \$25 fine, but they were taking licenses away from merchants because they were doing it four times a year. If they had three infractions in a row, they would lose their license for a month and that really hurt. So some communities are not even using fines. They are just going straight to the license suspension.

But there is no research comparing communities using different levels of fines. I know in Canada, they have \$5,000 to \$10,000 as fines for selling to minors, but then they are afraid to give out the fines.

Senator FRIST. Right. Thank you. I have just one final question, then Senator DeWine, if you have a final question.

Mr. Schwab, you work with State agencies in developing plans to reduce youth access, and it sounds like real progress has been made over the last 5 years. It may not be sufficient nor as far as we would like to go, that real progress has been made. What have the State agencies identified as their biggest hurdles?

Mr. SCHWAB. Well, it varies by State. In fact, we are kind of working with them at this point in terms of working through what are, indeed, some of the key barriers. For example, some of the States have talked about funding as being an important barrier as far as their own enforcement is concerned, and as part of that, we are looking at ways in which States have been creative about that, ways in which other areas have been looking at different policies and regulations that are in the State that may need to be changed.

For example, I think it is something on the order of not more than about 30 or 35 States have all of the retailers licensed and there are a number of States where that does not exist. Also, of those 30-plus States where, in fact, the retail outlets are licensed, maybe only about half, if that many, have revocation of licenses as part of any kind of a penalty structure.

So there are a number of areas there that we are looking at and that we have discussed with the States. Some of it, actually, in some areas, has to do with other parts, for example, where you have a significant number of merchants or retail clerks that may

not be English speaking and that that has been a barrier in terms of the education program and focusing attention in terms of having some culturally and linguistically-specific education materials. So there really are some areas that cover both that dimension as well as the enforcement area.

Dr. DIFRANZA. If I might add to that, a lot of the barriers to enforcing the law in these States have been sponsored by the Convenience Store Association to try to impede the enforcement of the law, putting loopholes in the law so that prosecutions become impossible, limiting the number of people in the State who can enforce the law sometimes to a single individual in the entire State, or stripping all police and health officials of the ability to enforce the law and only allowing the Agriculture Department, for instance, to enforce the law. So some of the barriers that the States are facing in enforcing the law have actually been set up by the tobacco industry for that purpose.

Senator FRIST. Thank you.

Senator DeWine, anything further?

Senator DEWINE. Nothing further, Mr. Chairman.

Senator FRIST. I want to thank all of our witnesses who spoke at our forum today for their excellent testimony, which will be very helpful in our deliberations. We have all benefited from their testimony and their insight.

I do want to thank everybody for coming to what was our earlier hearing and evolved into a public forum. Again, I am grateful to all my colleagues and witnesses for participating. Thank you.

[Whereupon, at 4:30 p.m., the subcommittee was adjourned.]

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